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Food and Drugs

21

PARTS 1 TO 99

Revised as of April 1, 1989

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PARTS 1 TO 99

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AS OF APRIL 1, 1989

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gton, D.C. 20402

Cite this Code: **CFR**

To cite the regulations in this volume use title, part and section number. Thus, 21 CFR 1.1 *refers to Title 21, Part 1, section 1.*

Explanation

The Code of Federal Regulations is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. The Code is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is divided into chapters which usually bear the name of the issuing agency. Each chapter is further subdivided into parts covering specific regulatory areas.

ISSUE DATES

Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16	as of January 1
Title 17 through Title 27	as of April 1
Title 28 through Title 41	as of July 1
Title 42 through Title 50	as of October 1

The appropriate revision date is printed on the cover of each volume.

LEGAL STATUS

The contents of the Federal Register are required to be judicially noticed (44 U.S.C. 1507). The Code of Federal Regulations is prima facie evidence of the text of the original documents (44 U.S.C. 1510).

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The Paperwork Reduction Act of 1980 (Pub. L. 96-511) requires Federal agencies to display an OMB control number with their information collection request. Many agencies have begun publishing numerous OMB control numbers as amendments to existing regulations in the CFR. These OMB numbers are placed as close as possible to the applicable recordkeeping or reporting requirements.

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Provisions that become obsolete before the revision date stated on the cover of each volume are not carried. Code users may find the text of provisions in effect on a given date in the past by using the appropriate numerical list of sections affected. For the period before January 1, 1973, consult either the List of CFR Sections Affected, 1949-1963, or 1964-1972, published in three separate volumes. For the period beginning January 1, 1973, a "List of CFR Sections Affected" is published at the end of each CFR volume.

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What is incorporation by reference? Incorporation by reference was established by statute and allows Federal agencies to meet the requirement to publish regulations in the Federal Register by referring to materials already published elsewhere. For an incorporation to be valid, the Director of the Federal Register must approve it. The legal effect of incorporation by reference is that the material is treated as if it were published in full in the Federal Register (5 U.S.C. 552(a)). This material, like any other properly issued regulation, has the force of law.

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(b) The matter incorporated is in fact available to the extent necessary to afford fairness and uniformity in the administrative process.

(c) The incorporating document is drafted and submitted for publication in accordance with 1 CFR Part 51.

Properly approved incorporations by reference in this volume are listed in the Finding Aids at the end of this volume.

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A subject index to the Code of Federal Regulations is contained in a separate volume, revised annually as of January 1, entitled CFR INDEX AND FINDING AIDS. This volume contains the Parallel Table of Statutory Authorities and Agency Rules (Table I), and Acts Requiring Publication in the Federal Register (Table

III). A list of CFR Titles, Chapters, and Parts and an alphabetical list of agencies publishing in the CFR are also included in this volume.

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There are no restrictions on the republication of material appearing in the Code of Federal Regulations.

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For a summary, legal interpretation, or other explanation of any regulation in this volume, contact the issuing agency. Inquiries concerning editing procedures and reference assistance with respect to the Code of Federal Regulations may be addressed to the Director, Office of the Federal Register, National Archives and Records Administration, Washington, D.C. 20408 (telephone 202-523-3517). Sales are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402 (telephone 202-783-3238).

Martha L. Girard
Acting Director,
Office of the Federal Register.

April 1, 1989.

THIS TITLE

Title 21—Food and Drugs is composed of nine volumes. The parts in these volumes are arranged in the following order: Parts 1-99, 100-169, 170-199, 200-299, 300-499, 500-599, 600-799, 800-1299 and 1300-End. The first eight volumes, containing Parts 1-1299, comprise Chapter I—Food and Drug Administration, Department of Health and Human Services. The ninth volume, containing Part 1300 to End, includes Chapter II—Drug Enforcement Administration, Department of Justice. The contents of these volumes represent all current regulations codified under this title of the CFR as of April 1, 1989.

The Table of Excepted Prescription Drugs to Part 1308 appears in the volume containing Part 1300-End.

Redesignation tables for Chapter I—Food and Drug Administration appear in the Finding Aids section of the first eight volumes.

For this volume, Ina C. Masters was Chief Editor. The *Code of Federal Regulations* publication program is under the direction of Richard L. Claypoole, assisted by Ruth C. Pontius.

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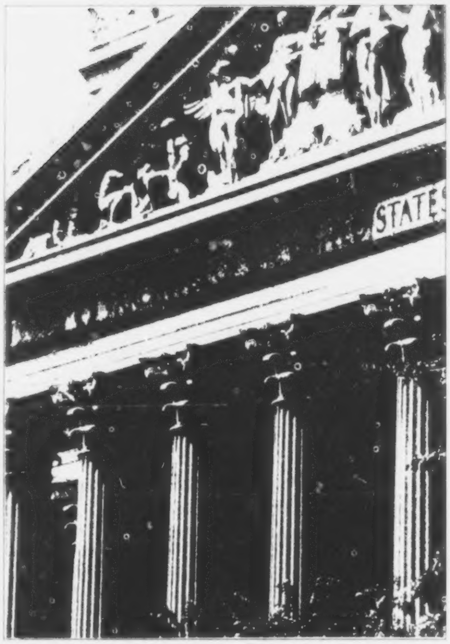

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Title 21—Food and Drugs

(This book contains Parts 1 to 99)

Part

CHAPTER I —Food and Drug Administration, Department of Health and Human Services 1

CROSS REFERENCES: Food Safety and Inspection Service, Department of Agriculture: See Meat and Poultry Inspection, 9 CFR Chapter III.

Federal Trade Commission: See Commercial Practices, 16 CFR Chapter I.

U.S. Customs Service, Department of the Treasury: See Customs Duties, 19 CFR Chapter I.

Internal Revenue Service, Department of the Treasury: See Internal Revenue, 26 CFR Chapter I.

Bureau of Alcohol, Tobacco, and Firearms, Department of the Treasury: See Alcohol, Tobacco Products and Firearms, 27 CFR Chapter I.

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

(Parts 1 to 99)

EDITORIAL NOTES: 1. Nomenclature changes affecting this chapter appear at 45 FR 40976, June 17, 1980, and 46 FR 8454, Jan. 27, 1981.

2. Food and Drug Administration published a document at 49 FR 41019, Oct. 19, 1984, establishing July 1, 1987, as a uniform effective date for compliance for regulations affecting the labeling of food products. At 51 FR 34085, Sept. 25, 1986, FDA established January 1, 1989 as a new uniform effective date for compliance. The new uniform effective date will apply only to final FDA food labeling regulations published after July 1, 1986, and before January 1, 1988.

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SUBCHAPTER A—GENERAL

PART 1—GENERAL REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

Subpart A—General Provisions

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1.95 Application for authorization to relabel and recondition.
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1.99 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.

AUTHORITY: Secs. 4, 5, 6 (15 U.S.C. 1453, 1454, 1455); secs. 201, 403, 502, 505, 512, 602, 701 (21 U.S.C. 321, 343, 352, 355, 360b, 362, 371).

SOURCE: 42 FR 15553, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 1.1 General.

(a) The provisions of regulations promulgated under the Federal Food, Drug, and Cosmetic Act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in regulations promulgated under that act.

(c) The definition of "package" in § 1.20 and of "principal display panel" in §§ 101.1, 201.60, 501.1, 701.10 and 801.60 of this chapter; and the requirements pertaining to uniform location, lack of qualification, and separation of the net quantity declaration in §§ 101.105(f), 201.62(e), 501.105(f), 701.13(f) and 801.62(e) of this chapter to type size requirements for net quantity declaration in §§ 101.105(i), 201.62(h), 501.105(i), 701.13(i) and 801.62(h) of this chapter, to initial statement of ounces in the dual declaration of net quantity in §§ 101.105(j) and (m), 201.62(i) and (k), 501.105(j) and (m), 701.13(j) and (m) and 801.62(i) and (k) of this chapter, to initial statement of inches in declaration of net quantity in §§ 201.62(m), 701.13(o) and 801.62(m) of this chapter, to initial statement of square inches in declaration of net quantity in §§ 201.62(n), 701.13(p) and 801.62(n) of this chapter, to prohibition of certain supplemental net quantity statements in §§ 101.105(o), 201.62(o), 501.105(o), 701.13(q) and 801.62(o) of this chapter, and to servings representations in §§ 101.8 and 501.8 of this chapter are provided for solely by the Fair Packaging and Labeling Act. The other requirements of this part are issued under both the Fair Packaging and Labeling Act and the Federal Food, Drug, and Cosmetic Act, or by the latter act solely, and are not limited in their application by section 10 of the Fair Packaging and Labeling Act.

§ 1.3 Definitions.

(a) Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(b) "Label" means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

§ 1.4 Authority citations.

(a) For each part or each subpart of its regulations, the Food and Drug Administration includes a centralized citation of all of the statutory provisions that provide authority for any regulation that is included in that part or subpart.

(b) The agency may rely on any one or more of the authorities that are listed for a particular part or subpart in implementing or enforcing any section in that part or subpart.

(c) All citations of authority in this chapter will list the applicable sections in the organic statute (e.g., the Federal Food, Drug, and Cosmetic Act), as well as the corresponding United States Code (U.S.C.) sections, if they exist. Where there is no corresponding U.S.C. provision, the agency will include a citation to the U.S. Statutes at Large. Citations to the U.S. Statutes at Large will refer to section, page, and volume.

(d) The authority citations will include a citation to executive delegations (i.e., Executive Orders), if any, necessary to link the statutory authority to the agency.

[53 FR 2828, Feb. 2, 1988]

Subpart B—General Labeling Requirements

§ 1.20 Presence of mandatory label information.

The term "package" means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

(a) Shipping containers or wrappings used solely for the transportation of any such commodity in bulk or in quantity to manufacturers, packers, processors, or wholesale or retail distributors;

(b) Shipping containers or outer wrappings used by retailers to ship or deliver any such commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or

(c) Containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231-233), the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234-236), the Act of August 31, 1916 (39 Stat. 673, as amended; 15 U.S.C. 251-256), or the Act of May 21, 1928 (45 Stat. 635, as amended; 15 U.S.C. 257-257i).

(d) Containers used for tray pack displays in retail establishments.

(e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part.

A requirement contained in this part that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or information also appears on the outer container or wrapper of the retail package of the article, or, as stated in paragraph (e) of this section, such information is easily legible by virtue of the transparency of the outer wrapper or container. Where a consumer commodity is marketed in a multiunit retail package bearing the mandatory label information as required by this part and the unit containers are not intended to be sold separately, the net weight placement requirement of § 101.105(f) applicable to such unit containers is waived if the units are in compliance with all the other requirements of this part.

§ 1.21 Failure to reveal material facts.

(a) Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are:

(1) Material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or

(2) Material with respect to consequences which may result from use of the article under: (i) The conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

(b) Affirmative disclosure of material facts pursuant to paragraph (a) of this section may be required, among other appropriate regulatory procedures, by

(1) Regulations in this chapter promulgated pursuant to section 701(a) of the act; or

(2) Direct court enforcement action.

(c) Paragraph (a) of this section does not:

(1) Permit a statement of differences of opinion with respect to warnings (including contraindications, precautions, adverse reactions, and other information relating to possible product hazards) required in labeling for food, drugs, devices, or cosmetics under the act.

(2) Permit a statement of differences of opinion with respect to the effectiveness of a drug unless each of the opinions expressed is supported by substantial evidence of effectiveness as defined in sections 505(d) and 512(d) of the act.

§ 1.23 Procedures for requesting variations and exemptions from required label statements.

Section 403(e) of the act (in this Part 1, the term "act" means the Federal Food, Drug, and Cosmetic Act) provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 403(i) of the act provides for the establishment by regulation of exemptions from the required declaration of ingredients where such declaration is impracticable, or results in deception or unfair competition. Section 502(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 602(b) of the act provides for the establishment by regulation of reasonable variations and exemptions for small packages from the required declaration of net quantity of contents. Section 5(b) of the Fair Packaging and Labeling Act provides for the establishment by regulation of exemptions from certain required declarations of net quantity of contents, identity of commodity, identity and location of manufacturer, packer, or distributor, and from declaration of net quantity of servings represented, based on a finding that full compliance with such required declarations is impracticable or not necessary for the adequate protection of consumers, and a further finding that the nature, form, or quantity of the packaged consumer commodity or other good and sufficient reasons justify such exemptions. The Commissioner, on his own initiative or on petition of an interested person, may propose a variation or exemption based upon any of the foregoing statutory provisions, including proposed findings if section 5(b) of the Fair Packaging and Labeling Act applies, pursuant to Parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 1.24 Exemptions from required label statements.

The following exemptions are granted from label statements required by this part:

(a) *Foods.* (1) While held for sale, a food shall be exempt from the required declaration of net quantity of contents specified in this part if said food is received in bulk containers at a retail establishment and is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.

(2) Random food packages, as defined in § 101.105(j) of this chapter, bearing labels declaring net weight, price per pound or per specified number of pounds, and total price shall be exempt from the type size, dual declaration, and placement requirements of § 101.105 of this chapter if the accurate statement of net weight is presented conspicuously on the principal display panel of the package. In the case of food packed in random packages at one place for subsequent shipment and sale at another, the price sections of the label may be left blank provided they are filled in by the seller prior to retail sale. This exemption shall also apply to uniform weight packages of cheese and cheese products labeled in the same manner and by the same type of equipment as random food packages exempted by

this paragraph (a)(2) except that the labels shall bear a declaration of price per pound and not price per specified number of pounds.

(3) Individual serving-size packages of foods containing less than ½ ounce or less than ½ fluid ounce for use in restaurants, institutions, and passenger carriers, and not intended for sale at retail, shall be exempt from the required declaration of net quantity of contents specified in this part.

(4) Individually wrapped pieces of "penny candy" and other confectionery of less than one-half ounce net weight per individual piece shall be exempt from the labeling requirements of this part when the container in which such confectionery is shipped is in conformance with the labeling requirements of this part. Similarly, when such confectionery items are sold in bags or boxes, such items shall be exempt from the labeling requirements of this part, including the required declaration of net quantity of contents specified in this part when the declaration on the bag or box meets the requirements of this part.

(5) (i) Soft drinks packaged in bottles shall be exempt from the placement requirements for the statement of identity prescribed by § 101.3 (a) and (d) of this chapter if such statement appears conspicuously on the bottle closure. When such soft drinks are marketed in a multiunit retail package, the multiunit retail package shall be exempt from the statement of identity declaration requirements prescribed by § 101.3 of this chapter if the statement of identity on the unit container is not obscured by the multiunit retail package.

(ii) A multiunit retail package for soft drinks shall be exempt from the declaration regarding name and place of business required by § 101.5 of this chapter if the package does not obscure the declaration on unit containers or if it bears a statement that the declaration can be found on the unit containers and the declaration on the unit containers complies with § 101.5 of this chapter. The declaration required by § 101.5 of this chapter may appear on the top or side of the closure of bottled soft drinks if the statement is conspicuous and easily legible.

(iii) Soft drinks packaged in bottles which display other required label information only on the closure shall be exempt from the placement requirements for the declaration of contents prescribed by § 101.105(f) of this chapter if the required content declaration is blown, formed, or molded into the surface of the bottle in close proximity to the closure.

(iv) Where a trademark on a soft drink package also serves as, or is, a statement of identity, the use of such trademark on the package in lines not parallel to the base on which the package rests shall be exempted from the requirement of § 101.3(d) of this chapter that the statement be in lines parallel to the base so long as there is also at least one statement of identity in lines generally parallel to the base.

(v) A multiunit retail package for soft drinks in cans shall be exempt from the declaration regarding name and place of business required by § 101.5 of this chapter if the package does not obscure the declaration on unit containers or if it bears a statement that the declaration can be found on the unit containers and the declaration on the unit containers complies with § 101.5 of this chapter. The declaration required by § 101.5 of this chapter may appear on the top of soft drinks in cans if the statement is conspicuous and easily legible, provided that when the declaration is embossed, it shall appear in type size at least one-eighth inch in height, or if it is printed, the type size shall not be less than one-sixteenth inch in height. The declaration may follow the curvature of the lid of the can and shall not be removed or obscured by the tab which opens the can.

(6) (i) Ice cream, french ice cream, ice milk, fruit sherbets, water ices, quiescently frozen confections (with or without dairy ingredients), special dietary frozen desserts, and products made in semblance of the foregoing, when measured by and packaged in ½-liquid pint and ½-gallon measure-containers, as defined in the "Measure Container Code of National Bureau of Standards Handbook 44," Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 "Meas-

ure-Containers," which is incorporated by reference, are exempt from the requirements of § 101.105(b)(2) of this chapter to the extent that net contents of 8-fluid ounces and 64-fluid ounces (or 2 quarts) may be expressed as ½ pint and ½ gallon, respectively. Copies are available from the Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition (HFF-310), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(ii) The foods named in paragraph (a)(6)(i) of this section, when measured by and packaged in 1-liquid pint, 1-liquid quart, and ½-gallon measure-containers, as defined in the "Measure Container Code of National Bureau of Standards Handbook 44," Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 "Measure-Containers," which is incorporated by reference, are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter. Copies are available from the Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition (HFF-310), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(iii) The foods named in paragraph (a)(6)(i) of this section, when measured by and packaged in ½-liquid pint, 1-liquid pint, 1-liquid quart, ½-gallon, and 1-gallon measured-containers, as defined in the "Measure Container Code of National Bureau of Standards Handbook 44," Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices, Sec. 4.45 "Measure-Containers," which is incorporated by reference, are exempt from the requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel. Copies are available from the Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition (HFF-310), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(7) (i) Milk, cream, light cream, coffee or table cream, whipping cream, light whipping cream, heavy or heavy whipping cream, sour or cultured sour cream, half-and-half, sour or cultured half-and-half, reconstituted or recombined milk and milk products, concentrated milk and milk products, skim or skimmed milk, vitamin D milk and milk products, fortified milk and milk products, homogenized milk, flavored milk and milk products, buttermilk, cultured buttermilk, cultured milk or cultured whole buttermilk, low-fat milk (0.5 to 2.0 percent butterfat), and acidified milk and milk products, when packaged in containers of 8- and 64-fluid-ounce capacity, are exempt from the requirements of § 101.105(b)(2) of this chapter to the extent that net contents of 8 fluid ounces and 64 fluid ounces (or 2 quarts) may be expressed as ½ pint and ½ gallon, respectively.

(ii) The products listed in paragraph (a)(7)(i) of this section, when packaged in glass or plastic containers of ½-pint, 1-pint, 1-quart, ½-gallon, and 1-gallon capacities are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel, provided that other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic container that is at or above the shoulder of the container.

(iii) The products listed in paragraph (a)(7)(i) of this section, when packaged in containers of 1-pint, 1-quart, and ½-gallon capacities are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter.

(8) Wheat flour products, as defined by §§ 137.105, 137.155, 137.160, 137.165, 137.170, 137.175, 137.180, 137.185, 137.200, and 137.205 of this chapter, packaged:

(i) In conventional 2-, 5-, 10-, 25-, 50-, and 100-pound packages are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the area of the principal display panel of the label; and

(ii) In conventional 2-pound packages are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter provided the quantity of contents is expressed in pounds.

(9) (i) Twelve shell eggs packaged in a carton designed to hold 1 dozen eggs and designed to permit the division of such carton by the retail customer at the place of purchase into two portions of one-half dozen eggs each are exempt from the labeling requirements of this part with respect to each portion of such divided carton if the carton, when undivided, is in conformance with the labeling requirements of this part.

(ii) Twelve shell eggs packaged in a carton designed to hold 1 dozen eggs are exempt from the placement requirements for the declaration of contents prescribed by § 101.105(f) of this chapter if the required content declaration is otherwise placed on the principal display panel of such carton and if, in the case of such cartons designed to permit division by retail customers into two portions of one-half dozen eggs each, the required content declaration is placed on the principal display panel in such a manner that the context of the content declaration is destroyed upon division of the carton.

(10) Butter as defined in 42 Stat. 1500 (excluding whipped butter):

(i) In 8-ounce and in 1-pound packages is exempt from the requirements of § 101.105(f) of this chapter that the net contents declaration be placed within the bottom 30 percent of the area of the principal display panel;

(ii) In 1-pound packages is exempt from the requirements of § 101.105(j)(1) of this chapter that such declaration be in terms of ounces and pounds, to permit declaration of "1-pound" or "one pound"; and

(iii) In 4-ounce, 8-ounce, and 1-pound packages with continuous label copy wrapping is exempt from the requirements of §§ 101.3 and 101.105(f) of this chapter that the statement of identity and net contents declaration appear in lines generally parallel to the base on which the package rests as it is designed to be displayed, provided that such statement and declaration are not so positioned on the label as to be misleading or difficult to read as the package is customarily displayed at retail.

(11) Margarine as defined in § 166.110 of this chapter and imitations thereof in 1-pound rectangular packages, except for packages containing whipped or soft margarine or packages that contain more than four sticks, are exempt from the requirement of § 101.105(f) of this chapter that the declaration of the net quantity of contents appear within the bottom 30 percent of the principal display panel and from the requirement of § 101.105(j)(1) of this chapter that such declaration be expressed both in ounces and in pounds to permit declaration of "1-pound" or "one pound," provided an accurate statement of net weight appears conspicuously on the principal display panel of the package.

(12) Corn flour and related products, as they are defined by §§ 137.211, 137.215, and 137.230 through 137.290 of this chapter, packaged in conventional 5-, 10-, 25-, 50-, and 100-pound bags are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the area of the principal display panel of the label.

(13) (i) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass or plastic containers of ½-pint, 1-pint, 1-quart, ½-gallon, and 1-gallon capacities are exempt from the placement requirement of § 101.105(f) of this chapter that the declaration of net contents be located within the bottom 30 percent of the principal display panel: *Provided*, That other required label information is conspicuously displayed on the cap or outside closure and the required net quantity of contents declaration is conspicuously blown, formed, or molded into or permanently applied to that part of the glass or plastic con-

tainer that is at or above the shoulder of the container.

(ii) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of 1-pint, 1-quart, and ½-gallon capacities are exempt from the dual net-contents declaration requirement of § 101.105(j) of this chapter.

(iii) Single strength and less than single strength fruit juice beverages, imitations thereof, and drinking water when packaged in glass, plastic, or paper (fluid milk type) containers of 8- and 64-fluid-ounce capacity, are exempt from the requirements of § 101.105(b)(2) of this chapter to the extent that net contents of 8 fluid ounces and 64 fluid ounces (or 2 quarts) may be expressed as ½ pint (or half pint) and ½ gallon (or half gallon), respectively.

(14) The unit containers in a multiunit or multicomponent retail food package shall be exempt from compliance with the requirements of section 403 (e)(1), (g)(2), (i)(2), and (k) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor and label declaration of ingredients when (i) the multiunit or multicomponent retail food package labeling meets all the requirements of this part; (ii) the unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and (iii) each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth inch in height. The word "Individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

(b) *Drugs.* Liquid over-the-counter veterinary preparations intended for injection shall be exempt from the declaration of net quantity of contents in terms of the U.S. gallon of 231 cubic inches and quart, pint, and fluid-ounce subdivisions thereof as required by § 201.62 (b), (i), and (j) of this chapter, and from the dual declaration requirements of § 201.62(i) of this chapter, if such declaration of net quantity of contents is expressed in terms of the liter and milliliter, or cubic centimeter, with the volume expressed at 68° F (20° C).

(c) *Cosmetics.* Cosmetics in packages containing less than one-fourth ounce avoirdupois or one-eighth fluid ounce shall be exempt from compliance with the requirements of section 602(b)(2) of the Federal Food, Drug, and Cosmetic Act and section 4(a)(2) of the Fair Packaging and Labeling Act:

(1) When such cosmetics are affixed to a display card labeled in conformance with all labeling requirements of this part; or

(2) When such cosmetics are sold at retail as part of a cosmetic package consisting of an inner and outer container and the inner container is not for separate retail sale and the outer container is labeled in conformance with all labeling requirements of this part.

[42 FR 15553, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 47 FR 32421, July 27, 1982; 49 FR 13339, Apr. 4, 1984; 54 FR 9033, Mar. 3, 1989]

§ 1.31 Package size savings.

Any food, drug, cosmetic, or device that bears on the label or labeling a representation that the consumer commodity is being offered at a lower price per unit of weight, measure, or count because of economy resulting from the size of the container or quantity of its contents is subject to the following conditions:

(a) The container may bear a representation of economy by virtue of its size (for example, "economy size," "economy pack," "big value," "thrifty pack," "bargain size," "budget pack," etc.) only if:

(1) The sponsor of the economy size promotion at the same time offers the same brand of that commodity in at least one other packaged size or labeled form.

(2) Only one packaged or labeled form of that brand of commodity is labeled with an "economy size" representation.

(3) The sponsor of the economy size promotion and all subsequent levels of commerce sell the commodity labeled with an "economy size" representation

at a price per unit of weight, volume, measure, or count which is substantially reduced (i.e., at least 5 percent) from the actual price of all other packaged or labeled units of the same brand of that commodity offered simultaneously.

(b) The sponsor of the economy size promotion and all subsequent levels of commerce such as wholesalers and jobbers shall maintain for at least 1 year invoices or other records showing that the wholesale price per unit of weight, measure, or count in the economy size package is such that the retailers can sell the economy size container at a significantly lower price per unit.

§ 1.35 "Cents-off," or other savings representations.

Any food, drug, cosmetic, or device that bears on the label or labeling a representation that the consumer commodity is being offered for retail at a reduction in retail price is subject to the following conditions: *Provided, however,* That such conditions do not apply to any such savings representations initiated by persons who do not manufacture, package, or import such commodities and who do not prescribe or specify by any means the manner in which such commodities are packaged or labeled by a manufacturer, packager, or importer:

(a) A "cents-off," or other savings representation that states or implies a reduction in the ordinary and customary retail price may be used by a manufacturer, packer, distributor, or retailer, hereinafter known as the sponsor, initiating such promotion only if:

(1) An ordinary and customary selling price of such consumer commodity has been established at the retail level,

(2) The sponsor's selling price and the selling price at all subsequent levels of commerce such as wholesalers and jobbers has been reduced by at least the savings differential represented on the package or labeling, and

(3) The sponsor and all subsequent levels of commerce keep and maintain invoices or other records for each promotion and for all successive promotions which occur within a 12-month period for at least 1 year subsequent to the end of the year (calendar, fiscal, or market) in which the promotion occurs in order to show that the invoice cost to the retailer has been reduced in an amount sufficient to enable the retailer to pass the savings on to the purchaser.

(b) (1) Each "cents-off" price reduction representation imprinted on the package or label shall be limited to a phrase which reflects that the price marked by the retailer represents the savings in the amount of the "cents-off" the retailer's regular price, e.g., "Price Marked Is —— Cents Off the Regular Price," "Price Marked Is —— Cents-Off the Regular Price of This Package": *Provided,* The package or label may in addition bear in the usual pricing spot a form reflecting a space for the regular price, the represented "cents-off," and a space for the price to be paid by the consumer. The sponsor who sells the commodity at retail shall display the regular price, clearly and conspicuously designated as "regular price," on the package or label of the commodity or on a sign, placard, or shelf-marker placed in a position contiguous to the retail display of the "cents-off" marked commodity. The sponsor who does not sell at retail shall provide the retailer with a sign, placard, shelf-marker, or other device for the purpose of clearly and conspicuously displaying the retailer's regular price, designated as "regular price," in a position contiguous to the "cents-off" marked commodity.

(2) Other savings representations which appear on the label or labeling of a package, e.g., "bonus offer," "two-for-one sales," "one-cent sales," etc., are subject to the provisions of this section. Due to the infinite variety and scope of such promotions, the label format of such representations may differ from that set forth in paragraph (b)(1) of this section for "cents-off" promotions; however, such representations shall include all material facts relative to the offer and shall in no way be misleading

(3) For the purposes of this section, the terms "ordinary and customary" and "regular" when used with the term "price" mean the price at which a consumer commodity has been openly and actively sold in the most recent and regular course of business

in a particular retail outlet or a trade area for a reasonably substantial period of time (at least 30 days). For consumer commodities that fluctuate in price, the ordinary and customary price shall be the lowest price at which any substantial sales were made during said 30 days.

(c) Shipments of consumer commodities bearing "cents-off," or other savings representations to a given geographic trade area made by the sponsor initiating such promotion shall be in no greater volume than 50 percent of the total units of that identical consumer commodity distributed in the same geographic trade area during any period of 12 consecutive months comprising a calendar, fiscal, or market year.

(d) The "cents-off," or other savings promotion may not be employed by a sponsor on consumer commodities for distribution to a specific geographic trade area until after 1 month has elapsed since their last distribution of that identical consumer commodity bearing a savings representation to the same geographic trade area. The number of such promotions for that identical consumer commodity that may occur within a 12-month period comprising a calendar, fiscal, or market year shall not exceed a total of six with no more than three of any one type or kind (e.g., "cents-off," "bonus offer," "two-for-one sale," "1-cent sale," etc.), and the total period of time for all such promotions shall not exceed 6 months within that 12-month period.

(e) A newly developed consumer commodity, one which has been changed in a functionally significant respect, or one which is newly introduced into a given geographic trade area may be the subject of an "introductory offer" type promotion. Such offers are not considered subject to the provisions of paragraphs (a) through (d) of this section, provided:

(1) Each such labeled offer is clearly and conspicuously qualified with the phrase "Introductory Offer," and

(2) If the introductory offer promotion is in the form of a "cents-off" representation, each such labeled offer shall include clearly and conspicuously in immediate conjunction therewith the phrase "—— Cents Off the After-Introductory -Offer Price"; and

(3) Labeled representations do not exceed a period of 6 months duration.

Any subsequent price reduction promotion of the consumer commodity is subject to the provisions of paragraphs (a) through (d) of this section and shall be preceded by the 30-day period required for a determination of the ordinary and customary selling price in that retail establishment. At the time of making the introductory offer promotion, the sponsor must intend in good faith to offer the commodity alone, immediately following the introductory offer promotion, for a reasonably substantial period of time (at least 30 days) at the anticipated after-introductory-offer price. The sponsor of the introductory offer promotion and all subsequent levels of commerce shall sell the commodity at a reduction from their anticipated after-introductory-offer price which reduction shall be at least equal to the savings differential represented on the package or labeling. The sponsor and all subsequent levels of commerce shall maintain invoices and records for at least 1 year subsequent to the end of the year (calendar, fiscal, or market) in which such introductory offer occurs.

Subparts C—D [Reserved]

Subpart E—Imports and Exports

§ 1.83 Definitions.

For the purposes of regulations prescribed under section 801(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The term "owner" or "consignee" means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

(b) The term "district director" means the director of the district of the Food and Drug Administration having jurisdiction over the port of entry through which an article is imported or offered for import, or such officer of the district as he may designate to act in his behalf in administer-ing and enforcing the provisions of section 801 (a), (b), and (c).

§ 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the district director, the collector of customs having jurisdiction over the article shall give to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the district director or the collector of customs of the results of examination of the sample.

§ 1.91 Payment for samples.

The Food and Drug Administration will pay for all import samples which are found to be in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration district headquarters in whose territory the shipment was offered for import. Payment for samples will not be made if the article is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance or rendered not a food, drug, device, or cosmetic as set forth in § 1.95.

§ 1.94 Hearing on refusal of admission.

(a) If it appears that the article may be subject to refusal of admission, the district director shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing, the district director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

§ 1.95 Application for authorization to relabel and recondition.

Application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device or cosmetic may be filed only by the owner or consignee, and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

§ 1.96 Granting of authorization to relabel and recondition.

(a) When authorization contemplated by § 1.95 is granted, the district director shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or the U.S. Customs Service, as the case may be;

(4) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(5) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the district director may grant such additional time as he deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the district director.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

[42 FR 15553, Mar. 22, 1977, as amended at 54 FR 9033, Mar. 3, 1989]

§ 1.97 Bonds.

(a) The bonds required under section 801(b) of the act may be executed by the owner or consignee on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic, in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the district director is in full agreement with the action.

§ 1.99 Costs chargeable in connection with relabeling and reconditioning inadmissible imports.

The cost of supervising the relabeling or other action in connection with an import of food, drugs, devices, or cosmetics which fails to comply with the Federal Food, Drug, and Cosmetic Act shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 801(b) of the act, as amended. The cost of such supervision shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law.

(c) The charge for the services of the supervising officer, which shall include administrative support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-11/4 employee, except that such services performed by a customs officer and subject to the provisions of the act of February 13, 1911, as amended (sec. 5, 36 Stat. 901, as amended (19 U.S.C. 267)), shall be calculated as provided in that act.

(d) The charge for the service of the analyst, which shall include administrative and laboratory support, shall be computed at a rate per hour equal to 266 percent of the hourly rate of regular pay of a grade GS-12/4 employee. The rate per hour equal to 266 percent of the equivalent hourly rate of regular pay of the supervising officer (GS-11/4) and the analyst (GS-12/4) is computed as follows:

	Hours
Gross number of working hours in 52 40-hr weeks	2,080
Less:	
9 legal public holidays—New Years Day, Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day	72
Annual leave—26 d	208
Sick leave—13 d	104
Total	384
Net number of working hours	1,696
Gross number of working hours in 52 40-hr weeks	2,080
Working hour equivalent of Government contributions for employee retirement, life insurance, and health benefits computed at 8½ pct. of annual rate of pay of employee	176
Equivalent annual working hours	2,256
Support required to equal to 1 man-year	2,256
Equivalent gross annual working hours charged to Food and Drug appropriation	4,512

NOTE: Ratio of equivalent gross annual number of working hours charged to Food and Drug appropriation to net number of annual working hours 4,512/1,696=266 pct.

(e) The minimum charge for services of supervising officers and of analysts shall be not less than the charge for 1 hour, and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than ½ hour.

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

Subpart A—General Provisions

Sec.
2.5 Imminent hazard to the public health.
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Subpart B—Human and Animal Foods

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Subpart F—Caustic Poisons

2.110 Definition of ammonia under Federal Caustic Poison Act.

Subpart G—Provisions Applicable to Specific Products Subject to the Federal Food, Drug, and Cosmetic Act

2.125 Use of chlorofluorocarbon propellants in self-pressurized containers.

Authority: Sec. 701, 52 Stat. 1055-1056 as amended (21 U.S.C. 371), unless otherwise noted.

Source: 42 FR 15559, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 2.5 Imminent hazard to the public health.

(a) Within the meaning of the Federal Food, Drug, and Cosmetic Act an imminent hazard to the public health is considered to exist when the evidence is sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held. The "imminent hazard" may be declared at any point in the chain of events which may ultimately result in harm to the public health. The occurrence of the final anticipated injury is not essential to establish that an "imminent hazard" of such occurrence exists.

(b) In exercising his judgment on whether an "imminent hazard" exists, the Commissioner will consider the number of injuries anticipated and the nature, severity, and duration of the anticipated injury.

(Secs. 505, 507, 512, 52 Stat. 1051-53, as amended, 59 Stat. 463, as amended, 82 Stat. 343-51, 21 U.S.C. 355, 357, 360b; secs. 2, 3, 10(a), 74 Stat. 372-75, as amended, 378, 15 U.S.C. 1261-62, 1269)

§ 2.10 Examination and investigation samples.

(a)(1) When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated, in which case he shall collect as much as is available and reasonably accessible.

(2) The cost of twice the quantity so estimated exceeds $50.

(3) The sample cannot by diligent use of practicable preservation techniques available to the Food and Drug Administration be kept in a state in which it could be readily and meaningfully analyzed in the same manner and for the same purposes as the Food and Drug Administration's analysis.

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States.

(5) The sample is collected from a person named on the label of the article or his agent, and such person is also the owner of the article.

(6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon.

In addition to the quantity of sample set forth in this paragraph, the officer or employee shall, if practicable, collect such further amount as he estimates will be sufficient for use as trial exhibits.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the act, or otherwise subject to the prohibitions of the act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or

(2) The request is not made within a reasonable time before the trial of any case under the act, based on the sample to which such person or owner is a party. The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

(d) When an official sample of food, drug, or cosmetic is the basis of a notice given under section 305 of the act, or of a case under the act, and the person to whom the notice was given, or any person who is a party to the case, has no right under paragraph (c) of this section to a part of the sample, such person or his attorney or agent may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this section.

(e) The Food and Drug Administration is authorized to destroy:

(1) Any official sample when it determines that no analysis of such sample will be made;

(2) Any official sample or part thereof when it determines that no notice under section 305 of the act, and no case under the act, is or will be based on such sample;

(3) Any official sample or part thereof when the sample was the basis of a notice under section 305 of the act, and when, after opportunity for presentation of views following such notice, it determines that no other

such notice, and no case under the act, is or will be based on such sample;

(4) Any official sample or part thereof when the sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample;

(5) Any official sample or part thereof if the article is perishable;

(6) Any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;

(7) That part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

(Secs. 701, 702, 52 Stat. 1055, as amended; 1056, as amended; 21 U.S.C. 371, 372)

§ 2.19 Methods of analysis.

Where the method of analysis is not prescribed in a regulation, it is the policy of the Food and Drug Administration in its enforcement programs to utilize the methods of analysis of the Association of Official Analytical Chemists (AOAC) as published in the latest edition (13th Ed., 1980) of their publication "Official Methods of Analysis of the Association of Official Analytical Chemists," and the supplements thereto ("Changes in Methods" as published in the March issues of the "Journal of the Association of Official Analytical Chemists"), which are incorporated by reference, when available and applicable. Copies are available from the Association of Official Analytical Chemists, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201-3301, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. In the absence of an AOAC method, the Commissioner will furnish a copy of the particular method, or a reference to the published method, that the Food and Drug Administration will use in its enforcement program. Other methods may be used for quality control, specifications, contracts, surveys, and similar nonregulatory functions, but it is expected that they will be calibrated in terms of the method which the Food and Drug Administration uses in its enforcement program. Use of an AOAC method does not relieve the practitioner of the responsibility to demonstrate that he can perform the method properly through the use of positive and negative controls and recovery and reproducibility studies.

(Sec. 707, 57 Stat. 500; 21 U.S.C. 377)

[42 FR 15559, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 54 FR 9034, Mar. 3, 1989]

Subpart B—Human and Animal Foods

§ 2.25 Grain seed treated with poisonous substances; color identification to prevent adulteration of human and animal food.

(a) In recent years there has developed increasing use of poisonous treatments on seed for fungicidal and other purposes. Such treated seed, if consumed, presents a hazard to humans and livestock. It is not unusual for stocks of such treated food seeds to remain on hand after the planting season has passed. Despite the cautions required by the Federal Seed Act (53 Stat. 1275, as amended 72 Stat. 476, 7 U.S.C. 1551 et seq.) in the labeling of the treated seed, the Food and Drug Administration has encountered many cases where such surplus stocks of treated wheat, corn, oats, rye, barley, and sorghum seed had been mixed with untreated seed and sent to market for food or feed use. This has resulted in livestock injury and in legal actions under the Federal Food, Drug, and Cosmetic Act against large quantities of food adulterated through such admixture of poisonous treated seeds with good food. Criminal cases were brought against some firms and individuals. Where the treated seeds are prominently colored, buyers and users or processors of agricultural food seed for food purposes are able to detect the admixture of the poisonous seed and thus reject the lots; but most such buyers, users, and processors do not have the facilities or scientific equipment to determine the presence of the poisonous chemical at the time crops are delivered, in cases where the treated seeds have not been so colored. A suitable color for this use is one that is in sufficient contrast to the natural color of the food seed as to make admixture of treated, denatured seeds with good food easily apparent, and is so applied that it is not readily removed.

(b) On and after December 31, 1964, the Food and Drug Administration will regard as adulterated any interstate shipment of the food seeds wheat, corn, oats, rye, barley, and sorghum bearing a poisonous treatment in excess of a recognized tolerance or treatment for which no tolerance or exemption from tolerance is recognized in regulations promulgated pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act, unless such seeds have been adequately denatured by a suitable color to prevent their subsequent inadvertent use as food for man or feed for animals.

(c) Attention is called to the labeling requirements of the Federal Hazardous Substances Act, where applicable to denatured seeds in packages suitable for household use.

(Secs. 402(a), 408, 52 Stat. 1046, as amended; 68 Stat. 511; 21 U.S.C. 342(a), 348; sec. 2(f)(1), 74 Stat. 372; 15 U.S.C. 1261)

§ 2.35 Use of secondhand containers for the shipment or storage of food and animal feed.

(a) Investigations by the Food and Drug Administration, the National Communicable Disease Center of the U.S. Public Health Service, the Consumer and Marketing Service of the U.S. Department of Agriculture, and by various State public health agencies have revealed practices whereby food and animal feed stored or shipped in secondhand containers have been rendered dangerous to health. Such contamination has been the result of the original use of these containers for the storage and shipment of articles containing or bearing disease organisms or poisonous or deleterious substances.

(b) The Commissioner concludes that such dangerous or potentially dangerous practices include, but are not limited to, the following:

(1) Some vegetable growers and packers employ used poultry crates for shipment of fresh vegetables, including cabbage and celery. Salmonella organisms are commonly present on dressed poultry and in excreta and fluid exudates from dressed birds. Thus wooden crates in which dressed poultry has been iced and packed are potential sources of Salmonella or other enteropathogenic microorganisms that may contaminate fresh vegetables which are frequently consumed without heat treatment.

(2) Some potato growers and producers of animal feeds use secondhand bags for shipment of these articles. Such bags may have originally been used for shipping or storing pesticide-treated seed or other articles bearing or containing poisonous substances. Thus these secondhand bags are potential sources of contamination of the food or animal feed stored or shipped therein.

(c) In a policy statement issued April 11, 1968, the Food and Drug Administration declared adulterated within the meaning of section 402(a) of the Federal Food, Drug, and Cosmetic Act shipments of vegetables or other edible food in used crates or containers that may render the contents injurious to health. This policy statement is extended so that the Food and Drug Administration will regard as adulterated within the meaning of section 402(a) of the act shipments of vegetables, other edible food, or animal feed in used crates, bags, or other containers that may render the contents injurious to health.

(Secs. 402(a), 52 Stat. 1046, as amended; 21 U.S.C. 342(a).)

Subparts C—E [Reserved]

Subpart F—Caustic Poisons

§ 2.110 Definition of ammonia under Federal Caustic Poison Act.

For the purpose of determining whether an article containing ammonia is subject to the Federal Caustic Poison Act, the ammonia content is to be calculated as NH_3.

(Secs. 2, 9, 44 Stat. 1406, 1409; 15 U.S.C. 402, 409)

Subpart G—Provisions Applicable to Specific Products Subject to the Federal Food, Drug, and Cosmetic Act

AUTHORITY: Secs. 301, 402, 409, 501, 502, 505, 507, 512, 601, 701, 52 Stat. 1042-1043, as amended, 1046-1047, as amended, 1049-1054, as amended, 1055-1056 as amended, 59 Stat. 463, as amended, 72 Stat. 1785-1788, as amended, 82 Stat. 343-351 (21 U.S.C. 331, 342, 348, 351, 352, 355, 357, 360b, 361, 371); 21 CFR 5.10.

§ 2.125 Use of chlorofluorocarbon propellants in self-pressurized containers.

(a) As used in this section:

(1) "Chlorofluorocarbon" means any fully halogenated chlorofluoroalkane.

(2) "Propellant" means a liquefied or compressed gas that is used in whole or in part to expel from the same self-pressurized container or from a separate container a liquid or solid material different from the propellant, but the term does not include the use of a chlorofluorocarbon as an aerating agent for foamed or sprayed food products.

(b) Chlorofluorocarbons are widely used in products subject to the Federal Food, Drug, and Cosmetic Act, with the principal use being as propellants in self-pressurized containers. Information recently developed indicates that chlorofluorocarbons may reduce the amount of ozone in the stratosphere and thus increase the amount of ultraviolet radiation reaching the earth. An increase in ultraviolet radiation may increase the incidence of skin cancer, change the climate, and produce other effects of unknown magnitude on humans, animals, and plants. Chlorofluorocarbons may also affect the climate by increasing infrared absorption in the atmosphere.

(c) Except as provided in paragraph (e) of this section, any food, drug, device, or cosmetic in a self-pressurized container that contains a chlorofluorocarbon propellant is adulterated and/or misbranded in violation of the act, and any drug product in a self-pressurized container that contains a chlorofluorocarbon propellant is a new drug or a new animal drug.

(d) The use of a chlorofluorocarbon as a propellant in a self-pressurized container of a drug product will not result in the drug product being adulterated and/or misbranded provided a new drug application, a new animal drug application, or in the case of a certifiable antibiotic an antibiotic application for the drug product has been approved, a petition has been filed as provided by paragraph (f) of this section, and paragraph (e) of this section has been amended to specify the use as essential.

(e) The adulteration and misbranding provisions of paragraph (c) of this section shall not apply to the following essential uses of chlorofluorocarbons:

(1) Metered-dose steriod human drugs for nasal inhalation,

(2) Metered-dose steriod human drugs for oral inhalation,

(3) Metered-dose adrenergic bronchodilator human drugs for oral inhalation,

(4) Contraceptive vaginal foams for human use, and

(5) Metered-dose ergotamine tartrate drug products administered by oral inhalation for use in humans.

(6) Intrarectal hydrocortisone acetate for human use.

(7) Polymyxin B sulfate-bacitracin zinc-neomycin sulfate soluble antibiotic powder without excipients, for topical use on humans.

(8) Anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for application.

(9) Metered-dose nitroglycerin human drugs administered to the oral cavity.

(10) Metered-dose cromolyn sodium human drugs administered by oral inhalation.

(11) Metered-dose ipratropium bromide for oral inhalation.

(f) Any person may file a petition in accordance with Part 10 of this chapter to amend paragraph (e) of this section to specify a use of chlorofluorocarbons in a product as not being subject to the adulteration and misbranding provisions in paragraph (c) of this section. The petition must be supported by an adequate showing that:

(1) There are no technically feasible alternatives to the use of a chlorofluorocarbon in the product,

(2) The product provides a substantial health benefit, environmental benefit, or other public benefit that would not be obtainable without the use of the chlorofluorocarbon, and

(3) The use does not involve a significant release of chlorofluorocarbons into the atmosphere or that the release is warranted in view of the consequence if the use were not permitted.

(g) Any holder of an approved new drug application or new animal drug application for a drug product containing a chlorofluorocarbon in a self-pressurized container, except those drug products listed in paragraph (e) of this section, shall submit to the Food and Drug Administration on or before October 1, 1978, either a supplemental application providing for a revised formulation complying with the requirements of § 314.70 or § 514.8 of this chapter or a letter requesting that a new drug application or a new animal drug application for the drug product containing chlorofluorocarbon be withdrawn and that the right to a hearing on the withdrawal of the application is waived.

(h)(1) Each manufacturer of a drug product listed in paragraph (e) of this section that is not covered by an approved new drug application shall submit a new drug application in accord with § 314.50 of this chapter on or before June 15, 1978.

(2) The Food and Drug Administration may find that an abbreviated new drug application conforming to § 314.55 of this chapter is acceptable in lieu of a full new drug application for any product included in the classes of products in paragraph (e) of this section. A finding has been made that an ANDA may be submitted for the following products included in the classes of products listed in paragraph (e) of this section:

(i) Ergotamine tartrate supplied in a metered-dose aerosol form suitable for oral inhalation for the treatment of migraine headaches. Each measured dose must deliver a dose of the active ingredient equivalent to that contained in the product that has been the subject of a separate finding that an abbreviated new drug application is suitable.

(ii) Isoproterenol hydrochloride supplied in a metered-dose aerosol form suitable for oral inhalation for use as an adrenergic bronchodilator. Each measured dose must deliver a dose of the active ingredient equivalent to that contained in the products that have been the subject of a separate finding that an abbreviated new drug application is suitable.

(iii) Epinephrine, epinephrine bitartrate, or epinephrine hydrochloride (racemic) in a metered-dose aerosol form suitable for oral inhalation for use as an adrenergic bronchodilator. Each measured dose must deliver a dose of the active ingredient equivalent to that specified in an OTC proposed or final monograph issued under the provisions of 21 CFR Part 330.

(iv) Nonoxynol 9 in an aerosol foam suitable for vaginal administration as a contraceptive foam. The aerosol foam must contain 8 to 12.5 percent of nonoxynol 9.

(i) Any sponsor of an "Investigational New Drug Application" (IND) or "Notice of Claimed Exemption for a New Animal Drug" (INAD) for a drug product containing a chlorofluorocarbon shall:

(1) Amend the IND or INAD on or before December 15, 1978, to revise the formulation removing the chlorofluorocarbon.

(2) Submit the information required under paragraph (f) of this section to amend paragraph (e) of this section to show that the use of chlorofluorocarbon is essential, or

(3) Submit the information required under paragraph (j) of this section requesting that studies with the drug product containing a chlorofluorocarbon propellant be allowed to be performed.

(j) Any sponsor of an IND or INAD who wishes to initiate or continue a study beyond December 15, 1978 on a drug product containing a chlorofluorocarbon shall submit a petition in accordance with Part 10 of this chapter requesting that studies be permitted to collect the data to show that the use of the chlorofluorocarbon is an essential use. The petitions must be supported by the following:

(1) A description of the drug product.

(2) An explanation why a chlorofluorocarbon propellant is used in the product rather than another propellant or another dosage form of the product, and

(3) The benefit that the investigational product is believed to have and that the sponsor hopes to demonstrate by the studies.

(k) The Commissioner will initiate action to withdraw approval of an application or terminate an IND or INAD notice in accordance with the applicable provisions of section 505 of the act and parts 312 and 314 of this chapter, or section 512 of the act and Parts 511 and 514 of this chapter upon failure of a holder of an approved new drug application or approved new animal drug application or sponsor of an IND or INAD notice to comply with the applicable provisions of this section.

(l) Food, drug, device, or cosmetic products manufactured or packaged on or after December 15, 1978, and finished products initially introduced into interstate commerce on or after April 15, 1979, shall comply with this regulation.

[43 FR 11316, Mar. 17, 1978, as amended at 44 FR 3961, Jan. 19, 1979; 44 FR 30334, May 26, 1979; 45 FR 22902, April 4, 1980; 51 FR 4591, Feb. 6, 1986; 52 FR 15717, Apr. 30, 1987; 54 FR 9034, Mar. 3, 1989]

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

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5.10 Delegations from the Secretary, the Assistant Secretary for Health, and Public Health Service Officials.
5.11 Reservation of authority.

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5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.
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5.24 Authority relating to technology transfer.
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5.50 Notification to petitioners of determinations made on petitions for reclassification of medical devices.
5.52 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.
5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.
5.54 Determinations that medical devices present unreasonable risk of substantial harm.
5.55 Orders to repair or replace, or make refunds for, medical devices.
5.58 Orphan products.
5.59 Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.
5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, and color additives.
5.62 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food matters.
5.63 Detention of meat, poultry, eggs, and related products.
5.66 Approval of schools providing food-processing instruction.
5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses or revocation of licenses and certain notices of revocation of licenses.
5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

Sec.
5.69 Notification of release for distribution of biological products.
5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962.
5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.
5.73 Certification of insulin.
5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin.
5.75 Designation of official master and working standards for antibiotic drugs.
5.76 Certification of antibiotic drugs.
5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.
5.80 Approval of new drug applications and their supplements.
5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.
5.83 Approval of new animal drug applications and their supplements.
5.84 Issuance of notices, proposals, and orders relating to new animal drugs and feeds bearing or containing new animal drugs.
5.86 Variances from performance standards for electronic products.
5.87 Exemption of electronic products from performance standards and prohibited acts.
5.88 Testing programs and methods of certification and identification for electronic products.
5.89 Notification of defects in, and repair or replacement of, electronic products.
5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.
5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.
5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.
5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.
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Subpart C—Organization

5.100 Headquarters.
5.105 Chief Counsel, Food and Drug Administration.
5.110 FDA Public Information Offices.
5.115 Field structure.

AUTHORITY: 5 U.S.C. 504, 552; 7 U.S.C. 2217; 15 U.S.C. 638, 1451 *et seq.*; 3701 *et seq.* 21 U.S.C. 41 *et seq.*, 61-63, 141 *et seq.*, 301-392, 467f(b), 679(b), 801 *et seq.*, 823(f), 1031 *et seq.*; 35 U.S.C. 156; 42 U.S.C. 219, 241, 242(a), 242a, 242l; 242o, 243, 262, 263, 263b through 263m, 264, 265, 300u *et seq.*, 1395y and 1395y note, 3246b(b)(3), 4831(a), 10007, and 10008; Federal Caustic Poison Act (44 Stat. 1406); Federal Advisory Committee Act (Pub. L. 92-463); E.O. 11490, 11921, 12591.

SOURCE: 42 FR 15560, Mar. 22, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes affecting Part 5 appear at 49 FR 14931, Apr. 16, 1984.

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

§ 5.10 Delegations from the Secretary, the Assistant Secretary for Health, and Public Health Service Officials.

(a) The Assistant Secretary for Health has redelegated to the Commissioner of Food and Drugs, with authority to redelegate except when specifically prohibited, all authority delegated to the Assistant Secretary for Health by the Secretary of Health and Human Services, as follows:

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Filled Milk Act (21 U.S.C. 61-63), the Federal Import Milk Act (21 U.S.C. 141 et seq.), the Tea Importation Act (21 U.S.C. 41 et seq.), the Federal Caustic Poison Act (44 Stat. 1406), and The Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), pursuant to section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in the Secretary of Agriculture by 7 U.S.C. 2217.

(2) Functions vested in the Secretary under section 301 (Research and Investigations); section 307 (International Cooperation); and section 311 (Federal-State Cooperation) of the Public Health Service Act (42 U.S.C. 241, 242*l*, 243), as amended, which relate to the functions of the Food and Drug Administration.

(3) Functions vested in the Secretary under sections 354 through 360F of

the Public Health Service Act (42 U.S.C. 263b through 263n), as amended, which relate to electronic product radiation control.

(4) Functions vested in the Secretary under section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, which relate to the law enforcement functions of the Food and Drug Administration concerning the following products and activities: biologicals (including blood and blood products); interstate travel sanitation (except interstate transportation of etiologic agents under 42 CFR 72); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration.

(5) Functions vested in the Secretary under sections 351 and 352 of Part F, Subpart 1 of the Public Health Service Act (42 U.S.C. 262 and 263), as amended, Biological Products, insofar as they relate to the functions assigned to the Food and Drug Administration.

(6) Functions vested in the Secretary under section 302(a) of the Public Health Service Act (42 U.S.C. 242(a)), as amended, which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.

(7) Functions vested in the Secretary under section 303 of the Public Health Service Act (42 U.S.C. 242a), as amended, which relate to the authorization of persons engaged in research on the use and effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Pub. L. 91-513 for which an investigational new drug application is filed with the Food and Drug Administration and with respect to all drugs not scheduled under Pub. L. 91-513.

(8) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.

(9) Functions vested in the Secretary pertaining to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) which relate to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act, and the merits of the research protocol.

(10) Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 et seq.) which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(11) Functions vested in the Secretary under section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(12) Functions vested in the Secretary under section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(13) Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(14) Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

(15) Function of issuing all regulations of the Food and Drug Administration, except as provided in § 5.11. The reservation of authority contained in Chapter 2-000 of the Department Organization Manual shall not apply.

(16) Functions vested in the Secretary under section 1103 of Executive Order 11490, as amended by Executive Order 11921, which relate to emergency health functions as they pertain to the operations and functional responsibilities assigned to the agency. This authority shall be exercised in accordance with section 102 and pertinent sections of Part 30 of Executive Order 11490 and guidelines promulgated by the Federal Preparedness Agency of the General Services Administration; Office of the Secretary, HHS; and Office of the Assistant Secretary for Health.

(17) Function vested in the Secretary of authorizing and approving mis-

cellaneous and emergency expenses of enforcement activities.

(18) Function vested in the Secretary under the Federal Advisory Committee Act, Pub. L. 92-463, to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefor may be closed to the public for those committees under the administrative jurisdiction of the Commissioner of Food and Drugs. This authority may not be redelegated. This authority is to be exercised in accordance with the requirements of the Act and only with respect to the following:

(i) Meetings, to the extent that they directly involve review, discussion or consideration of records of the Department which are exempt from disclosure under 5 U.S.C. 552(b) (4), (6), and (7), namely, (*a*) records containing trade secrets and commercial or financial information obtained from a person and privileged or confidential; (*b*) personnel, medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (*c*) investigatory files compiled for law enforcement purposes;

(ii) Meetings to the extent that they involve the review, discussion, and evaluation of specific drugs and devices regulated by FDA which are intended to result in recommendations for regulatory decisions under the Federal Food, Drug, and Cosmetic Act and which are concerned with matters listed in 5 U.S.C. 552(b) (4), (5), and (7);

(iii) Meetings held for the sole purpose of considering and formulating advice which the committee will give or any final report it will render, *Provided:*

(*a*) The meetings will involve solely the internal expression of views and judgments of the members and it is essential to close the meeting or portions thereof to protect the free exchange of such views and avoid undue interference with agency or committee operations, and such views if reduced to writing would be protected from mandatory disclosure under 5 U.S.C. 552(b);

(*b*) The meeting is closed for the shortest time necessary, summarizing the work of the committee during the closed session, and a report, prepared by the executive secretary will be made available promptly to the public.

(*c*) When feasible, the public is given a timely opportunity to present relevant information and views to the committee; and

(*d*) Concurrence for closing the meetings for such purpose is obtained from the Office of the General Counsel and the Office of Public Affairs.

(19) Functions vested in the Secretary under the second sentence of section 310(a) and under section 310(b) (Health Conferences and Health Education Information) of the Public Health Service Act (42 U.S.C. 242o), as amended, to call for a conference and invite as many health authorities and officials of State or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of the Food and Drug Administration, and to issue information related to health for the use of the public and other pertinent health information for the use of persons and institutions concerned with health services when such information is related to the functions of the Food and Drug Administration.

(20) Functions vested in the Secretary under section 2101 of the Public Health Service Act (42 U.S.C. 219) as amended, to accept offers of gifts, excluding the acceptance of gifts of real property. Only the authority to accept unconditional gifts of personal property valued at $5,000 or less may be redelegated.

(21) Functions vested in the Secretary under section 362 of the Public Health Service Act (42 U.S.C. 265), as amended, which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of the Food and Drug Administration.

(22) Functions vested in the Secretary under section 1003(b)(3), Title X, of the Public Works and Economic Development Act of 1965 (42 U.S.C.

3246b(b)(3)) to waive any matching requirements for programs or projects of State and local governments funded under Title X of that act where it is determined that State or local governments concerned cannot reasonably obtain any non-Federal contributions.

(23) Functions vested in the Secretary under section 401(a) of the Lead-Based Paint Poisoning Prevention Act, as amended by Pub. L. 94-317 (42 U.S.C. 4831(a)) relating to the prohibition of the application of lead-based paint to cooking, drinking, or eating utensils.

(24) Functions vested in the Secretary for the health information and health promotion program under Title XVII of the Public Health Service Act (42 U.S.C. 300u et seq.), as amended, insofar as the authorities pertain to functions assigned to the Food and Drug Administration. The delegation includes, but is not limited to, the authorities under: section 1702(a) (1) and (3) and section 1704 (1), (2), and (6). The delegation excludes the authority to select all Senior Executive Service, supergrade and equivalent, and Schedule C (GS-12 and above) positions; promulgate regulations; and submit reports to the President.

(25) To administer a Small Business Innovation Research Program under section 9 of the Small Business Act (15 U.S.C. 638), as amended. The delegation excludes the authority to promulgate regulations, establish advisory councils and committees, appoint members to advisory councils and committees, and submit reports to Congress.

(26) Functions vested in the Secretary under sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981 (42 U.S.C. 10007 and 10008), as amended. The delegation excludes the authority to promulgate regulations and submit reports to Congress. The authority delegated under section 983 of the Act may only be exercised as it relates to functions assigned to the Food and Drug Administration.

(27) Functions vested in the Secretary under section 156 of title 35 of the U.S. Code (35 U.S.C. 156), as amended, which allows for the extension of patent terms for human drug products, medical devices, food additives, and color additives subject to the Federal Food, Drug, and Cosmetic Act. These authorities may be redelegated except the authority to make due diligence determinations under section 156(d)(2)(B), which may not be redelegated to an Office below the Office of the Commissioner of Food and Drugs.

(28) Functions vested in the Secretary under section 1862(h) (1), (2)(A), and (3) of the Social Security Act (42 U.S.C. 1395y (h)(1), (2)(A), and (3)), as amended, which provides for a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under this title. The approval and issuance of regulations under that section are reserved to the Secretary, as provided in 21 CFR 5.11.

(29) Functions vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 et seq.) (the Act), as amended, and under Executive Order No. 12591 of April 10, 1987, as they pertain to the functions of the Food and Drug Administration. The delegation excludes the authority to promulgate regulations and submit reports to Congress; under section 11(a)(2) of the Act (15 U.S.C. 3710a(a)(2)) to approve agreements and contracts with invention management organizations; and under section 11(c)(3)(B) of the Act (15 U.S.C. 3710a(c)(3)(B)) to propose necessary statutory changes regarding conflict of interest.

(i) The authorities under sections 11(c)(5) (A) and (B) of the Act (15 U.S.C. 3710a(c)(5) (A) and (B)) to disapprove or require the modification of cooperative research and development agreements and licensing agreements after the agreement is presented to the Commissioner of Food and Drugs by the head of the laboratory concerned, and to transmit written explanation of such disapproval or modification to the head of the laboratory concerned, may be redelegated only to a senior official in the immediate office of the Commissioner.

(ii) The following authorities may not be redelegated: the authority under section 11(b)(3) of the Act (15 U.S.C. 3710a(b)(3)) to waive a right of ownership which the Federal Government may have to an invention made under a cooperative research and development agreement; the authority under section 11(b)(4) of the Act (15 U.S.C. 3710a(b)(4)) to permit employees or former employees to participate in efforts to commercialize inventions they made while in the service of the United States; the authority under section 11(c)(3)(A) of the Act (15 U.S.C. 3710a(c)(3)(A)) to review employee standards of conduct for resolving potential conflicts of interest; the authority under section 13(a)(1) of the Act (15 U.S.C. 3710c(a)(1)) to retain any royalties or other income, except as provided in section 13(a)(2) of the Act (15 U.S.C. 3710c(a)2)); and the authority under section 13(a)(1)(A)(i) of the Act (15 U.S.C. 3710c(a)(1)(A)(i)) to pay royalties or other income the agency receives on account of an invention to the inventor if the inventor was an employee of the agency at the time the invention was made.

(iii) Any authorities under paragraph (a)(29) of this section delegated by the Commissioner of Food and Drugs may not be further redelegated.

(b) The Assistant General Counsel in charge of the Food and Drug Division has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act, section 4 of the Federal Import Milk Act, and section 9(b) of the Federal Caustic Poison Act.

(c) The Director, Office of Management, Public Health Service, has redelegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the nonexistence of records on file within the Administration; and to cause the Seal of the Department of be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(d) The Executive Officer, Public Health Service, has redelegated to the Commissioner of Food and Drugs appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's record when the appeal has been made by the individual under Privacy Act regulations (Part 21 of this chapter and 45 CFR Part 5b). The authority may not be redelegated.

(e) [Reserved]

(f) The Secretary of Health and Human Services has redelegated to the Commissioner of Food and Drugs, or his designee, the authority to take final action on matters pertaining to section 203 of the Equal Access to Justice Act (5 U.S.C. 504), and to develop procedures and regulations where necessary to supplement the Department's regulations, 45 CFR Part 13.

[42 FR 15560, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 5.10, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 5.11 Reservation of authority.

(a) Notwithstanding provisions of § 5.10 or any previous delegations of authority to the contrary, the Secretary reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of Title 5 of the United States Code apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of Title 5 of the United States Code apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food and Drug Administration without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

[47 FR 16318, Apr. 16, 1982]

Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs is redelegated as set forth in this subpart.

(b) The Deputy Commissioner and the Associate Commissioner for Regulatory Affairs are authorized to perform all of the functions of the Commissioner of Food and Drugs.

(c) During the absence or disability of the Commissioner or in the event of a vacancy in that position, the first official who is available in the following positions, or who has been designated by the Commissioner to act in such position, shall act as Commissioner:

(1) Deputy Commissioner.

(2) Associate Commissioner for Regulatory Affairs.

(3) Associate Commissioner for Management and Operations.

For a planned period of absence, the Commissioner may specify a different order of succession.

(d) Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him as "acting" or unless not legally permissible.

(e) Authority delegated in the following sections of this subpart may not be redelegated.

[43 FR 20487, May 12, 1978, as amended at 48 FR 43300, Sept. 23, 1983]

§ 5.21 Emergency functions.

Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his region, to fully represent the Food and Drug Administration within his region in consonance with the Department of Health and Human Services regional emergency plans and to exercise the authority of the Commissioner for supervision of and direction to all Food and Drug Administration activities and use of resources within his region for continuity and for Federal Emergency Health Service operations. These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters.

§ 5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of or extracts from any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the nonexistence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

(1) The Associate and Deputy Associate Commissioners.

(2)(i) The Director, Office of the Executive Assistant.

(ii) The Director, Executive Secretariat.

(iii) The Director, Program Management Staff.

(3) The Executive Officer, Office of the Commissioner.

(4)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).

(ii) The Director and Deputy Director, Office of Regional Operations, ORA.

(iii) The Director and Deputy Director, Office of Regulatory Resource Management ORA.

(iv) The Chief, Administrative Management Staff, Office of Regulatory Resource Management, ORA.

(5)(i) The Director, Division of Management Systems and Policy, Office of Management and Operations (OMO).

(ii) The Chief, Dockets Management Branch, Division of Management Systems and Policy, OMO.

(6) The Director, Freedom of Information Staff, Office of Public Affairs.

(7)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director, Office of Management, CBER.

(iii) The Directors and Deputy Directors of the Offices of Compliance, Biological Product Review and Biologics Research, CBER.

(iv) The Chiefs of the Case Management Staff and the Inspections and Surveillance Staff, Regulations and Bioresearch Monitoring Staff, Office of Compliance, CBER.

(v) The Chief, Biologics Information Staff, Office of Biological Product Review, CBER.

(8)(i) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Management, CFSAN.

(iii) The Director, Office of Compliance, CFSAN.

(iv) The Director, Division of Regulatory Guidance, and the Director, Division of Cooperative Programs, Office of Compliance, CFSAN.

(v) The Director, Division of Food Chemistry and Technology, Office of Physical Sciences, CFSAN.

(9)(i) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(ii) The Director, Office of Management Services, CDRH.

(iii) The Director and Deputy Director, Office of Compliance, CDRH.

(iv) The Director, Division of Compliance Operations, Office of Compliance, CDRH.

(v) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

(vi) Freedom of Information Officers, Office of Standards and Regulations, CDRH.

(10)(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Management, CVM.

(iii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iv) The Director and Deputy Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(11)(i) The Director and Deputy Director, National Center for Toxicological Research (NCTR).

(ii) The Director, Office of Management, NCTR.

(12)(i) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Management, Epidemiology and Biostatistics, Compliance, Drug Evaluation I, Drug Evaluation II, Drug Standards, and Research Resources, CDER.

(iii) The Chief, Freedom of Information Staff and Freedom of Information Officers, Office of Management, CDER.

(iv) The Directors of the Divisions of Drug Labeling Compliance, Drug Quality Evaluation, and Manufacturing and Product Quality, Office of Compliance, CDER.

(13)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) The Director, St. Louis Branch.

(iv) The Director, Winchester Engineering and Analytical Center.

(v) The Director, New York Laboratory Division, Northeast Region.

(vi) The Director, Science Division, Southeast Region.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

(1) The Associate and Deputy Associate Commissioners.

(2) The Director, Division of Human Resources Management, Office of Management and Operations.

(c) The Chief, Regulations Editorial Staff and his/her alternates, Division of Regulations Policy, Office of Enforcement, ORA, are authorized to certify true copies of FEDERAL REGISTER documents.

[50 FR 4858, Feb. 4, 1985, as amended at 51 FR 11428, Apr. 3, 1986; 51 FR 32452, Sept. 12, 1986; 51 FR 41765, Nov. 19, 1986; 52 FR 41986, Nov. 2, 1987; 54 FR 8315, Feb. 28, 1989; 54 FR 11866, Mar. 22, 1989]

§ 5.23 Disclosure of official records.

(a) The following officials are authorized to make determinations to disclose official records and information under Part 20 of this chapter, except that only the officials listed in paragraph (a)(1) may disclose official records and information under §§ 20.82 and 20.85 of this chapter.

(1) Associate and Deputy Associate Commissioners.

(2)(i) The Director, Office of the Executive Assistant.

(ii) The Director, Executive Secretariat.

(iii) The Director, Program Management Staff.

(3) Executive Officer, Office of the Commissioner.

(4) The Chief, Dockets Management Branch, Division of Management Systems and Policy, Office of Management and Operations.

(5) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(6) Regional Food and Drug Directors and District Directors.

(7) Director, Winchester Engineering and Analytical Center.

(8) Chiefs of branches Field/District Offices and Centers.

(9) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(b) The Chief, Drug Listing Branch, Division of Drug Labeling Compliance, Office of Compliance, Center for Drug Evaluation and Research (CDER), is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records:

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director, Division of Product Surveillance, Office of Compliance, CDRH.

(d) The Chief of the Records Section of the Administrative Services Branch, Division of Management Services, Office of Management and Operations, is authorized to sign affidavits regarding the presence or absence of records in the files of that section.

(e) The Director and Deputy Director, Division of Product Certification, Office of Biological Product Review, Center for Biologics Evaluation and Research, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments.

[43 FR 29286, July 7, 1978, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 51 FR 11428, Apr. 3, 1986; 54 FR 8315, Feb. 28, 1989]

§ 5.24 Authority relating to technology transfer.

(a) The Associate Commissioner for Regulatory Affairs is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under sections 11(c)(5) (A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended.

(b) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 et seq.), as amended, and Executive Order 12591 of April 10, 1987, except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(29) of this part, as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner of Food and Drugs to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with section 11(c)(5)(A) of the Act (15 U.S.C. 3710a(c)(5)(A):

(1) The Director, Center for Biologics Evaluation and Research.

(2) The Director, Center for Devices and Radiological Health.

(3) The Director, Center for Drug Evaluation and Research.

(4) The Director, Center for Food Safety and Applied Nutrition.

(5) The Director, Center for Veterinary Medicine.

(6) The Director, National Center for Toxicological Research.

(7) The Associate Commissioner for Regulatory Affairs.

[53 FR 26049, July 11, 1988]

§ 5.25 Research, investigation, and testing programs and health information and health promotion programs.

(a) The following officials are authorized under sections 301, 307, 311, 1701, 1702, 1703, and 1704 of the Public Health Service Act (the act) to establish research, investigation, and testing programs and health information and health promotion programs, which relate to their assigned functions, and to approve grants for conducting such programs:

(1) The Director and Deputy Director, National Center for Toxicological Research.

(2) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(3) The Director and Deputy Director, Center for Biologics Evaluation and Research.

(4) The Director and Deputy Director, Center for Food Safety and Applied Nutrition.

(5) The Director and Deputy Director, Center for Veterinary Medicine.

(6) The Director and Deputy Director, Center for Drug Evaluation and Research.

(b) The Director and Deputy Director, CDRH, are authorized to establish an electronic product radiation control program and to approve grants for conducting the program under section 356 of the act.

(c) The Associate and Deputy Associate Commissioner for Management and Operations, the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Management and Operations, the Chief of the State Contracts and Assistance Agreements Branch, and the Chief of the Grants and Assistance Agreements Section of that Division and Office are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof for grants approved under the authority delegated in paragraphs (a) and (b) of this section.

(d) The Director of the National Center for Toxicological Research is authorized under section 301, as amended by Pub. L. 95--622, of the Public Health Service Act to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of the Center which are not required to support Center research programs.

[45 FR 7783, Feb. 5, 1980, as amended at 45 FR 27924, Apr. 25, 1980; 46 FR 17758, Mar. 20, 1981; 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 54 FR 8316, Feb. 28, 1989]

§ 5.26 Service fellowships.

The following officials are authorized to designate persons to receive service fellowships in the Food and Drug Administration Staff Fellowship Program under section 207(g) of the Public Health Service Act:

(a) Associate and Deputy Associate Commissioners.

(b) The Director and Deputy Director, National Center for Toxicological Research (NCTR), and the Director, Office of Management, NCTR.

(c) The Director and Deptuy Director, Center for Devices and Radiological Health (CDRH), and the Director, Office of Management Services, CDRH.

(d) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director, Office of Mangement, CBER.

(e) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN), and Director, Office of Management, CFSAN.

(f) The Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director, Office of Management, CVM.

(g) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), and the Director and Deputy Director, Office of Management, CDER.

(h) The Director, Office of Regulatory Resource Management, Office of Regulatory Affairs.

[48 FR 56946, Dec. 27, 1983, as amended at 49 FR 14932, 14936, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 54 FR 8316, Feb. 28, 1989]

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives.

The Associate Commissioner for Health Affairs is authorized to perform the functions delegated to the Commissioner under section 156 of Title 35 of the U.S. Code (35 U.S.C. 156), except for the holding of informal hearings pursuant to 35 U.S.C. 156(d)(2)(B)(ii).

[50 FR 9424, Mar. 8, 1985]

§ 5.28 Cardiac pacemaker devices and pacemaker leads.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under the Social Security Act (42 U.S.C. 1395y(h)(1), (2)(A), and (3)), as amended.

[51 FR 25883, July 17, 1986]

§ 5.30 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act; section 6 of the Fair Packaging and Labeling Act; section 9(b) of the Federal Caustic Poison Act; and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), and the Directors and Deputy Directors of the Offices of Drug Evaluation I, Drug Evaluation II, and Compliance, CDER.

(3) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(4) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(5) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Director, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the Public Health Service Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing pursuant to the provisions of Part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of § 16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Associate Commissioner for Health Affairs.

(2) The Director and Deputy Director, CFSAN.

(3) The Director and Deputy Director, CDER, and the Directors and Deputy Directors of the Offices of Drug Evaluation I, Drug Evaluation II, and Compliance.

(4) The Director and Deputy Director, CDRH.

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Director, CBER, and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

[48 FR 8440, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8316, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989]

§ 5.31 Petitions under Part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors of the Offices of Biological Product Review and Biologics Research, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Biological Product Review and Biologics Research, CBER.

(2)(i) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(b) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting in vitro test modifications under § 331.29 of this chapter:

(1) The Director and Deputy Director, CDER.

(2) The Director and Deputy Director, Office of Drug Standards, CDER.

(3) The Director and Deputy Director, Division of OTC Drug Evaluation, Office of Drug Standards, CDER.

(c) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in § 211.132, § 700.25, or § 800.12 of this chapter for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director and Deputy Director, CDER, and the Director and Deputy Director, Office of Complince, CDER.

(2) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Compliance, CFSAN.

(3) The Director and Deputy Director, Center for Devices and Radiological Health.

(d) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting exemption from the general pregnancy nursing warning for over-the-counter (OTC) drugs required under § 201.63 of this chapter:

(1) The Director and Deputy Director, CDER.

(2) The Director and Deputy Director, Office of Drug Standards, CDER.

(e)(1) The Director and Deputy Director, CFSAN, are authorized to issue 180-day tentative responses to citizen petitions on food matters under

§ 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(2) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(3) The Director and Deputy Director, CBER, are authorized to issue 180-day tentative responses to citizen petitions on biological product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(4) The Director and Deputy Director, CDER, are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(f)(1) The Director and Deputy Director, CBER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug and biological product matters in program areas where they have been delegated final approval authority in the following sections of this part:

(i) Section 5.68 *Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products;*

(ii) Section 5.69 *Notification of release for distribution of biological products;*

(iii) Section 5.71 *Termination of exemptions for new drugs for investigational use in human beings or in animals;*

(iv) Section 5.80 *Approval of new drug applications and their supplements;* and

(v) Section 5.82 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.*

(2) The Director and Deputy Director, CDER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug product matters in program areas where they have been delegated final approval authority in the following sections of this part:

(i) Section 5.70 *Issuance of notices implementing the provisions of the Drug Amendments of 1962 (DESI);*

(ii) Section 5.71 *Termination of exemptions for new drugs for investigational use in human beings or in animals;*

(iii) Section 5.73 *Certification of insulin;*

(iv) Section 5.74 *Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin;*

(v) Section 5.75 *Designation of official master and working standards for antibiotic drugs;*

(vi) Section 5.76 *Certification of antibiotic drugs;*

(vii) Section 5.78 *Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs;*

(viii) Section 5.80 *Approval of new drug applications and their supplements;* and

(ix) Section 5.82 *Issuance of notices relating to proposals to refuse aproval or to withdraw approval of new drug applications and their supplements.*

(3) The Director and Deputy Director, Office of Drug Standards, CDER, except for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(4) The Director and Deputy Director, Office of Biological Product Review, CBER, for those drug products listed in § 314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(5) For drugs assigned to their organization, the following officials are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter from sponsors of an investigational new drug application who request approval to ship in interstate commerce, in accordance with § 2.125(j) of this chapter, an investiga-

tional new drug for human use containing a chlorofluorocarbon.

(i) The Director and Deputy Director, CBER.

(ii) The Director and Deputy Director, CDER.

(6) The Director and Deputy Director, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter from sponsors of an investigational new animal drug application who request approval to ship in interstate commerce, in accordance with § 21.125(j) of this chapter, an investigational new animal drug for animal use containing a chlorofluorocarbon.

(7) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, are authorized to issue responses to citizen petitions submitted under § 10.30 of this chapter, seeking a determination of the suitability of an abbreviated new animal drug application for an animal drug product.

[47 FR 38480, Aug. 31, 1982, as amended at 47 FR 54757, Dec. 3, 1982; 47 FR 55471, Dec. 10, 1982; 48 FR 56946, Dec. 27, 1983; 49 FR 5094, Feb. 10, 1984; 49 FR 14933, 14936, Apr. 16, 1984; 50 FR 30696, July 29, 1985; 51 FR 17011, May 8, 1986; 52 FR 2514, Jan. 23, 1987; 54 FR 6884, Feb. 15, 1989; 54 FR 8316, Feb. 28, 1989]

§ 5.35 Enforcement activities.

(a) Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA-200A, Identification Record, and Form FDA-200B, Specification of General Authority, are authorized:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the Act); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Import Milk Act, the Filled Milk Act, the Tea Importation Act, and sections 351 and 354 through 361 of the Public Health Service Act.

(2) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) The Food and Drug Administration's official credentials referred to in paragraph (a) of this section are described as follows:

(1) Form FDA-200A entitled "Identification Record" bears a color photograph, a description, and the signature of the holder, an identification number, an expiration date, the Department of Health and Human Services' seal with blue imprint, on the left of the photograph, and the Food and Drug Administration's symbol, on the right of the photograph.

(2) Form FDA-200B entitled "Specification of General Authority" bears the holder's name, his or her general authority, an identification number, an expiration date, the Commissioner's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. The form is superimposed with the Department's seal with blue imprint.

[49 FR 19973, May 11, 1984, as amended at 53 FR 22293, June 15, 1988]

§ 5.36 Certification following inspections.

Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to issue certificates of sanitation under § 1240.20 of this chapter.

[51 FR 32452, Sept. 12, 1986]

§ 5.37 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 306 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

(1)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(2)(i) The Director and Deputy Director of the Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director, Division of Compliance Operations, Office of Compliance, CDRH.

(3)(i) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Compliance, CFSAN.

(iii) The Director, Division of Regulatory Guidance, Office of Compliance, CFSAN.

(4)(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director and Deputy Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(5)(i) The Director and Deputy Director, Center for Drug Evaluation and Resarch (CDER).

(ii) The Director and Deputy Director, Office of Compliance, CDER.

(6)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) Chiefs of District Compliance Branches.

(iv) The Director, St. Louis Branch.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 360C(d) of the Public Health Service Act regarding the issuance of written notices or warnings:

(1) The Director and Deputy Director of the Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director, Division of Compliance Operations, Office of Compliance, CDRH.

(4) Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, when such functions relate to:

(i) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter; and

(ii) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product as defined in § 1040.20(b) of this chapter.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14933, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989]

§ 5.44 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove applications to export unapproved new drugs and biological products and to issue notices of receipt of such applications:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(iii) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(iv) The Director and Deputy Director, Office of Compliance, CDER.

(2) For new animal drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) The following officials are authorized, under section 802(f) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, CBER.

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(iii) The Director and Deputy Director, CDER.

(iv) The Director and Deputy Director, Office of Compliance, CDER.

(2) For veterinary drugs subject to their jurisdiction:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(c) The following officials are authorized, under section 351(h) of the Public Health Service Act, to approve or disapprove an application to export a partially processed biological product:

(1) The Director and Deputy Director, CBER.

(2) The Director and Deputy Director, Office of Compliance, CBER.

[52 FR 7269, Mar. 10, 1987, as amended at 54 FR 8317, Feb. 28, 1989]

§ 5.45 Imports and exports.

(a) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized, under section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of food, drugs (including biological products), devices, or cosmetics imported or offered for import.

(2) Determine whether such articles are in compliance with the FFDCA.

(3) Authorize relabeling or other compliance actions to bring articles into compliance under the FFDCA.

(4) Supervise such compliance actions.

(b) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH); the Director and Deputy Director, Office of Compliance, CDRH; Regional Food and Drug Directors; District Directors; and the Director, St. Louis Branch, are authorized, under section 360 of the Public Health Service Act (PHSA), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of electronic products imported or offered for import to determine whether such products are in compliance with the PHSA.

(2) Refuse admission of noncomplying products and notify the Secretary of the Treasury of such refusal.

(3) Supervise operations to bring noncomplying products into compliance under the PHSA.

(4) Refuse or grant permission and time extensions to bring noncomplying products into compliance with the PHSA in accordance with a corrective action plan approved by the Director, Office of Compliance, CDRH.

(c) The following officials are authorized, under section 360B(b) of the PHSA, to exempt persons from issuing a certification, as required by section 358(h) of the PHSA, for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function will be destroyed or exported in accord with U.S. Customs Service's regulations:

(1) The Director and Deputy Director, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) Regional Food and Drug Directors.

(4) District Directors.

(5) The Director, St. Louis Branch.

(d) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to exercise all of the functions of the Commissioner of Food and Drugs under section 362 of the PHSA that refers to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to exportation of medical devices under section 801(e) of the FFDCA:

(1) For medical devices assigned to their respective organization:

(i) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(iv) The Director and Deputy Director, Office of Compliance, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs, for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the FFDCA for emergency medical care:

(1) The Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Compliance, CBER.

(2) The Director, Center for Drug Evaluation and Research (CDER) and the Director, Office of Compliance, CDER.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 572, Jan. 5, 1984; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 6518, Feb. 13, 1989; 54 FR 8317, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989]

§ 5.46 Manufacturer's resident import agents.

The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to reject manufacturer's designations of import agents under § 1005.25(b) of this chapter.

[48 FR 56947, Dec. 27, 1983]

§ 5.47 Detention of adulterated or misbranded medical devices.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act and in accordance with § 800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(a) For medical devices assigned to their respective organizations:

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(4) The Director and Deputy Director, Office of Compliance, CBER.

(b) Regional Food and Drug Directors.

(c) District Directors.

(d) The Director, St. Louis Branch.

[48 FR 8442, Mar. 1, 1983, as amended at 48 FR 56947, Dec. 27, 1983; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989]

§ 5.49 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

The following officials, for medical devices assigned to their respective organizations, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the act) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989]

§ 5.50 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections

513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the act (except for petitions submitted in response to FEDERAL REGISTER notices initiating standard-setting under section 514(b) of the act or premarket approval under section 515(b) of the act):

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 54 FR 11866, Mar. 22, 1989]

§ 5.52 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989]

§ 5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b)(1) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the act:

(i) The Director and Deputy Director, CDRH, and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(ii) The Director and Deputy Director, CBER, and the Director and Deputy Director, Office of Biological Product Review, CBER.

(2) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications.

(c) The Director and Deputy Director, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515 (d), (e), and (g) and 520(h)(1) of the act.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 21708, May 23, 1984; 50 FR 9424, Mar. 8, 1985; 54 FR 8317, Feb. 28, 1989]

§ 5.54 Determinations that medical devices present unreasonable risk of substantial harm.

The following officials, for medical devices assigned to their respective organizations, are authorized to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8318, Feb. 28, 1989]

§ 5.55 Orders to repair or replace, or make refunds for, medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to order repair or replacement of, or refund for, medical devices under section 518 (b) and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8318, Feb. 28, 1989]

§ 5.58 Orphan products.

(a) The Director, Office of Orphan Products Development, Office of the Commissioner, is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for establishment and product licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, Office of Orphans Products Development, Office of the Commissioner, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and Cosmetic Act (the act) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act.

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act.

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act.

(c) The following officials are authorized to provide sponsors, under section 525(a) of the act, with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(iii) The Division Directors of the divisions in the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(2) For biological products under their jurisdiction:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

[48 FR 40703, Sept. 9, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 27489, July 5, 1984; 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989]

§ 5.59 Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the act.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14934, Apr. 16, 1984; 54 FR 8318, Feb. 28, 1989]

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, and color additives.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 401, 409, and 706 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of notices of proposed rulemaking pertaining to food standards; and notices of filing, and voluntary withdrawal, of petitions on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the assigned functions of the respective Center:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(b)(1) The Director and Deputy Director, CFSAN, are authorized to perform all of the functions of the Commissioner of Food and Drugs under sections 409 and 706 of the act regarding the approval of the use of food additives under section 409(e) of the act and the listing of color additives other than those on the provisional list, under section 706(d) of the act (including notices of confirmation of effective date), where the listing does not involve novel or controversial issues and does not involve any question about the applicability of the Delaney Anti-Cancer Clause.

(2) The Director and Deputy Director, CFSAN, are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of notices of temporary permits for foods varying from standards of identity under § 130.17 of this chapter.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner of Food and Drugs regarding approvals of the use of food additives under section 409(e) of the act, where these approvals do not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(c)(1) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act or to color additive petitioners under section 706(d)(1) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CFSAN.

(ii) The Director, Office of Compliance, CFSAN.

(iii) The Director and Deputy Director, Division of Food and Color Additives, Office of Compliance, CFSAN.

(2) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to certify batches of color additives under section 706 of the act:

(1) The Director and Deputy Director, CFSAN.

(2) The Director and Deputy Director, Office of Physical Sciences, CFSAN.

(3) The Director and Deputy Director, Division of Color and Cosmetics, Office of Physical Sciences, CFSAN.

(e) The Director and Deputy Director, CFSAN, are authorized to issue advance notices of proposed rulemaking pertaining to Codex Alimentarius food standards, and notices terminating consideration of such standards when comments fail to support the desirability and need for proposing their adoption, under § 130.6 of this chapter.

(f) The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming generally recognized as safe (GRAS) status of food substances under §§ 170.35 or 570.35 of this chapter where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

(1) The Director and Deputy Director, CFSAN.

(2) The Director and Deputy Director, CVM.

[49 FR 14936, Apr. 16, 1984, as amended at 49 FR 48183, Dec. 11, 1984; 52 FR 5951, Feb. 27, 1987]

§ 5.62 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food matters.

The Director and Deputy Director, Center for Food Safety and Applied Nutrition, are authorized to issue initial emergency permit orders under § 108.5 of this chapter and notices of confirmation of effective date of final regulations on food matters promulgated under section 701(e) of the Federal Food, Drug, and Cosmetic Act.

[49 FR 14937, Apr. 16, 1984]

§ 5.63 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

[48 FR 8442, Mar. 1, 1983, as amended at 51 FR 32452, Sept. 12, 1986; 54 FR 9034, Mar. 3, 1989]

§ 5.66 Approval of schools providing food-processing instruction.

The Director and Deputy Director, Center for Food Safety and Applied Nutrition, are authorized to perform all the functions of the Commissioner of Food and Drugs under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections.

[49 FR 14937, Apr. 16, 1984]

§ 5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses or revocation of licenses and certain notices of revocation of licenses.

The Director and Deputy Director, Center for Biologics Evaluation and Research are authorized to issue:

(a) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for establishment or product licenses under § 601.4(b) of this chapter.

(b) Notices of opportunity for a hearing on proposals to revoke establishment or product licenses under § 601.5(b) of this chapter.

(c) Notices of revocation, at the manufacturer's request, of establishment or product licenses under §§ 601.5(a) and 601.8 of this chapter.

[50 FR 30697, July 29, 1985, as amended at 54 FR 8318, Feb. 28, 1989]

§ 5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The following officials are authorized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8318, Feb. 28, 1989]

§ 5.69 Notification of release for distribution of biological products.

The following officials are authorized to issue written notices of release for distribution of licensed biological products under Subchapter F (Parts 600 through 699) of this chapter:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

(c) The Director and Deputy Director, Division of Product Quality Control, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989]

§ 5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962.

The Director and Deputy Director, Center for Drug Evaluation and Research, are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the provisions of sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act.

[54 FR 8318, Feb. 28, 1989]

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under § 312.44 of this chapter and in animals under § 312.160 of this chapter:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under § 312.44(b)(1)(viii) of this chapter:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in § 312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I and Drug Evaluation II, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under § 511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 52 FR 7829, Mar. 13, 1987; 54 FR 8318, Feb. 28, 1989]

§ 5.73 Certification of insulin.

The following officials are authorized to certify or reject batches of drugs containing insulin pursuant to section 506(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

(c) The Director and Deputy Director, Division of Drug Quality Evaluation, Office of Compliance, CDER.

(d) The Chief and Assistant Chief, Product Surveillance Branch, Division of Drug Quality Evaluation, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 506 of the Federal Food, Drug, and Cosmetic Act regarding the issuance, amendment, or repeal of regulations pertaining to drugs containing insulin:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.75 Designation of official master and working standards for antibiotic drugs.

The following officials are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 430.5 of this chapter:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Research Resources, CDER.

(c) The Director and Deputy Director, Division of Research and Testing, Office of Research Resources, CDER.

[49 FR 27315, July 3, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.76 Certification of antibiotic drugs.

The following officials are authorized to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

(c) The Director and Deputy Director, Division of Drug Quality Evaluation, Office of Compliance, CDER.

(d) The Chief and Assistant Chief, Product Surveillance Branch, Division of Drug Quality Evaluation, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989]

§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use:

(1) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(b) The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the act regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use contained in medical devices.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14935, Apr. 16, 1984; 54 FR 8319, Feb. 28, 1989]

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act:

(i) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER, for drugs under their jurisdiction.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), for drugs listed in § 314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act.

(b) The officials listed in paragraphs (b) (1) and (2) of this section, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(1) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation I, CDER.

(2) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation II, CDER.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5C classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies.

(1) For drugs submitted under §§ 314.50, 314.55, and 314.70 of this chapter, except for those drug products listed in § 314.440(b):

(i) The Director and Deputy Director, Office of Drug Standards, CDER.

(ii) The Director and Deputy Director, Division of Generic Drugs, Office of Drug Standards, CDER.

(2)(i) For drug products listed in § 314.440(b) and submitted under §§ 314.50, 314.55, and 314.70 of this chapter:

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to new drug applications for human use that are described by § 314.70(b)(1) and (2)(ii) through (x) and (c)(1) and (3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph (d). The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in § 5.10(a), the introductory text, and paragraphs (a) and (b)(1) and (2) of this section.

(1) The supervisory chemists in the divisions in the Office of Drug Evaluation I, CDER.

(2) The supervisory chemists in the divisions in the Office of Drug Evaluation II, CDER.

[49 FR 14935, Apr. 16, 1984, as amended at 50 FR 30697, July 29, 1985; 50 FR 47207, Nov. 15, 1985; 52 FR 37764, Oct. 9, 1987; 54 FR 8319, Feb. 28, 1989]

§ 5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director and Deputy Director, Center for Drug Evaluation and Research, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and Subpart B of Part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research, for those drugs listed in § 314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and Subpart B of Part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

[54 FR 8319, Feb. 28, 1989]

§ 5.83 Approval of new animal drug applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted pursuant to section 512 of the act:

(1) The Director, the Deputy Director for Human Food Safety and Consultative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to new animal drug applications that are described by § 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Chemistry, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of applications for animal feeds containing new animal drugs:

(1) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(2) The Chief, Petition Review and Medicated Feeds Branch, Division of

Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Medicated Feeds Specialist, Petition Review and Medicated Feeds Branch, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

[49 FR 14937, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 53 FR 2225, Jan. 27, 1988; 53 FR 17186, May 16, 1988; 53 FR 40055, Oct. 13, 1988]

§ 5.84 Issuance of notices, proposals, and orders relating to new animal drugs and feeds bearing or containing new animal drugs.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and feeds bearing or containing new animal drugs, submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act;

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs, corresponding to said action on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

[49 FR 17936, Apr. 26, 1984]

§ 5.86 Variances from performance standards for electronic products.

The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in Subchapter J of this chapter:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

(c) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

[52 FR 29664, Aug. 11, 1987]

§ 5.87 Exemption of electronic products from performance standards and prohibited acts.

The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 358(a)(5) of the Public Health Service Act (the act) and to exempt an electronic product or class of products from all or part of the provisions of section 360B(a) of the act under section 360B(b) of that act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

(c) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

[52 FR 29664, Aug. 11, 1987]

§ 5.88 Testing programs and methods of certification and identification for electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to review and evaluate industry testing programs under section 358(g) of the Public Health Service Act (the act), and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 358(h) of the act.

[48 FR 56948, Dec. 27, 1983]

§ 5.89 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), are authorized to perform all functions of the Commissioner of Food and Drugs relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 359 of the Public Health Service Act (the act) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product, as defined in § 1040.20(b) of this chapter.

(b) The Director and Deputy Director, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 359(e) of the act and under § 1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-reay systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp products, as defined in § 1040.20(b) of this chapter.

[48 FR 56948, Dec. 27, 1983, as amended at 51 FR 32452, Sept. 12, 1986]

§ 5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

[48 FR 56948, Dec. 27, 1983]

§ 5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 360A(f) of the Public Health Service Act.

[48 FR 56948, Dec. 27, 1983]

§ 5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.

The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to accept assistance from State and local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

[48 FR 56949, Dec. 27, 1983]

§ 5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505(c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) of the Federal Food, Drug and Cosmetic Act (the act) concerning the date of submission or the date or effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act and of new drug applications including supplements thereto submitted under section 505(b)(1) of the act and described under section 505(b)(2) of the act:

(a) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Drug Standards, CDER.

[53 FR 18274, May 23, 1988]

§ 5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

The following officials are authorized to extend or stay an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(a) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Director, Office of Biological Product Review, CBER.

(3) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

(b) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER).

(2) The Directors and Deputy Directors of the Office of Drug Evaluation I and Drug Evaluation II, CDER.

(3) The Directors and Deputy Directors of the divisions in the Office of Drug Evaluation I and Drug Evaluation II, CDER.

[52 FR 2514, Jan. 23, 1987, as amended at 54 FR 8320, Feb. 28, 1989]

Subpart C—Organization

§ 5.100 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER [1]

Office of Regulatory Affairs.
Office of Management and Operations.
Office of Health Affairs.
Office of Science.
Office of Planning and Evaluation.
Office of Legislative Affairs.
Office of Public Affairs.
Office of Consumer Affairs.

CENTER FOR DRUG EVALUATION AND RESEARCH [1]

Office of Management

Division of Management and Budget.
Division of Information Systems Design.
Division of Drug Information Resources.
Medical Library.

Office of Epidemiology and Biostatistics

Division of Epidemiology and Surveillance.
Division of Biometrics.

Office of Compliance

Division of Drug Labeling Compliance.
Division of Drug Quality Evaluation.
Division of Manufacturing and Product Quality.
Division of Scientific Investigations.
Division of Regulatory Affairs.

Office of Drug Evaluation I

Division of Cardio-Renal Drug Products.
Division of Neuropharmacological Drug Products.
Division of Oncology and Radiopharmaceutical Drug Products.
Division of Surgical-Dental Drug Products.
Division of Gastrointestinal and Coagulation Drug Products.

Office of Drug Evaluation II

Division of Metabolism and Endocrine Drug Products.
Division of Anti-Infective Drug Products.
Division of Anti-Viral Drug Products.

Office of Drug Standards

Division of OTC Drug Evaluation.
Division of Generic Drugs.
Division of Bioequivalence.
Division of Biopharmaceutics.
Division of Drug Advertising and Labeling.

Office of Research Resources

Division of Research and Testing.
Division of Drug Analysis.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH [2]

Office of Management

Office of Compliance

Office of Biological Product Review

Division of Product Quality Control.
Division of Biological Investigational New Drugs.
Division of Product Certification.

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[1] Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

[2] Mailing address: 8800 Rockville Pike, Bldg. 29, Bethesda, MD 20814.

Office of Biologics Research

Division of Bacterial Products.
Division of Blood and Blood Products.
Division of Virology.
Division of Biochemistry and Biophysics.
Division of Cytokine Biology.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION [3]

Office of Management

Division of Program Operations.
Division of Administrative Operations.
Division of Information Resources Management.

Office of Compliance

Division of Regulatory Guidance.
Division of Food and Color Additives.
Division of Cooperative Programs.

Office of Toxicological Sciences

Division of Toxicological Studies.
Division of Toxicological Review and Evaluation.
Division of Pathology.
Division of Mathematics.

Office of Physical Sciences

Division of Contaminants Chemistry.
Division of Colors and Cosmetics.
Division of Food Chemistry and Technology.

Office of Nutrition and Food Sciences

Division of Consumer Studies.
Division of Nutrition.
Division of Microbiology.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH [1]

Office of Management Services

Division of Planning, Evaluation, and Information Services.
Division of Resource Management.

Office of Information Systems

Division of Computer Services.
Division of Information Resources.

Office of Health Physics

Office of Health Affairs [4]

Office of Standards and Regulations

Office of Compliance and Surveillance [4]

Division of Management Information.
Division of Compliance Programs.
Division of Compliance Operations.
Division of Product Surveillance.
Division of Standards Enforcement.

Office of Device Evaluation [4]

Division of Cardiovascular Devices.
Division of Gastroenterology/Urology and General Use Devices.
Division of Anesthesiology, Neurology, and Radiology Devices.
Division of Obstetrics/Gynecology, Ear, Nose, Throat, and Dental Devices.
Division of Surgical and Rehabilitation Devices.
Division of Clinical Laboratory Devices.
Division of Ophthalmic Devices.

Office of Science and Technology

Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.
Division of Biometric Sciences.
Division of Electronics and Computer Sciences.

Office of Training and Assistance

Division of Consumer Affairs.
Division of Small Manufacturers Assistance.
Division of Intergovernmental Programs.
Division of Technical Development.
Division of Professional Practices.
Division of Training Support.

CENTER FOR VETERINARY MEDICINE [1]

Office of Management

Office of New Animal Drug Evaluation

Division of Biometrics, Informatics, and Environmental Sciences.
Division of Chemistry.
Division of Therapeutic Drugs for Food Animals.
Division of Therapeutic Drugs for Non-Food Animals.
Division of Toxicology.
Division of Production Drugs.

Office of Surveillance and Compliance

Division of Compliance.
Division of Surveillance.
Division of Animal Feeds.
Division of Voluntary Compliance and Hearings Development.

Office of Science

Division of Veterinary Medical Research.

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[3] Mailing address: 200 C St. SW., Washington, DC 20204.

[4] Mailing address: 8757 Georgia Ave., Silver Spring, MD 20910.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH [8]

Office of Management

Division of Management Services.
Division of Resource Information Management Systems.
Division of Facilities Engineering and Maintenance.

Office of Research

Division of Reproductive and Developmental Toxicology.
Division of Genetic Toxicology.
Division of Biochemical Toxicology.
Division of Comparative Toxicology.
Division of Human Risk Assessment.

Office of Research Services

Division of Microbiology.
Division of Animal Husbandry.
Division of Chemistry.

[54 FR 11696, Mar. 22, 1989]

§ 5.105 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Assistant General Counsel, Food and Drug Division, Office of the General Counsel, Department of Health and Human Services, Room 6-57, 5600 Fishers Lane, Rockville, MD 20857.

[46 FR 8455, Jan. 27, 1981]

§ 5.110 FDA Public Information Offices.

(a) *Dockets Management Branch (HFA-305).* The Dockets Management Branch Public Room is located in Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-1753.

(b) *Freedom of Information Staff (HFI-35).* The Freedom of Information Public Room is located in Room 12A-30, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-6310.

(c) *Press Relations Staff (HFI-40).* Press Offices are located in Room 15-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-3285; and in Room 3807, FB-8, 200 C Street SW., Washington, D.C. 20204. Telephone: 202-245-1144.

[46 FR 8455, Jan. 27, 1981, as amended at 54 FR 9034, Mar. 3, 1989]

§ 5.115 Field structure.

NORTHEAST REGION

Regional Field Office: 830 Third Ave., Brooklyn, NY 11232.
New York District Office: 850 Third Ave., Brooklyn, NY 11232.
Boston District Office: One Montvale Ave., Stoneham, MA 02180.
Buffalo District Office: 599 Delaware Ave., Buffalo, NY 14202.

MID-ATLANTIC REGION

Regional Field Office: 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106.
Philadelphia District Office: 900 U.S. Customhouse, Second and Chestnut Sts., Philadelphia, PA 19106.
Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201.
Cincinnati District Office: 1141 Central Parkway, Cincinnati, OH 45202-1097.
Newark District Office: 61 Main St., West Orange, NJ 07052.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.
Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.
Nashville District Office: 297 Plus Park Blvd., Nashville, TN 37217.
New Orleans District Office: 4298 Elysian Fields, New Orleans, LA 70122.
Orlando District Office: 7200 Lake Ellenor Dr., Suite 120, Orlando, FL 32809.
San Juan District Office: Fernandez Juncos Ave., Stop 8½, Puerta de Tierra, San Juan, PR. Mail to: P.O. Box 5719, Puerta de Tierra Station, San Juan, PR 00906-5719.

MIDWEST REGION

Regional Field Office: 20 North Michigan Ave., Chicago, IL 60602.
Chicago District Office: 1222 PO Bldg., 433 West Van Buren St., Chicago, IL 60607.
Detroit District Office: 1560 East Jefferson, Detroit, MI 48207.
Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401.

SOUTHWEST REGION

Regional Field Office: 3032 Bryan St., Dallas, TX 75204.
Dallas District Office: 3032 Bryan St., Dallas, TX 75204.
Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225-0087.
Kansas City District Office: 1009 Cherry St., Kansas City, MO 64106.
St. Louis Branch: 308 North Collins Alley, St. Louis, MO 63102.

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[8] Mailing address: Jefferson, AR 72079.

PACIFIC REGION

Regional Field Office: Rm. 568 Federal Office Bldg., 50 U.N. Plaza, San Francisco, CA 94102.
San Francisco District Office: Rm. 526, Federal Office Bldg., 50 U.N. Plaza, San Francisco, CA 94102.
Los Angeles District Office: 1521 West Pico Blvd., Los Angeles, CA 90015-2486.
Seattle District Office: 22201 23d Dr. SE., Bothell, WA 98021-4421.

[54 FR 11697, Mar. 22, 1989]

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

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7.1 Scope.
7.3 Definitions.
7.12 Guaranty.
7.13 Suggested forms of guaranty.

Subpart B—[Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidelines on Policy, Procedures, and Industry Responsibilities

7.40 Recall policy.
7.41 Health hazard evaluation and recall classification.
7.42 Recall strategy.
7.45 Food and Drug Administration-requested recall.
7.46 Firm-initiated recall.
7.49 Recall communications.
7.50 Public notification of recall.
7.53 Recall status reports.
7.55 Termination of a recall.
7.59 General industry guidance.

Subpart D—[Reserved]

Subpart E—Criminal Violations

7.84 Opportunity for presentation of views before report of criminal violation.
7.85 Conduct of a presentation of views before report of criminal violation.
7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

AUTHORITY: Secs. 305, 701(a), 52 Stat. 1045, 1055 (21 U.S.C. 335, 371(a)), unless otherwise noted.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) and other laws that it administers. This part also provides guidelines for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

(Sec. 1 et seq., Pub. L. 717, 52 Stat. 1040-1059 as amended (21 U.S.C. 301 et seq.); secs. 301, 351, and 361, Pub. L. 410, 58 Stat. 691-703 as amended (42 U.S.C. 241, 262, and 264))

[43 FR 26218, June 16, 1978]

§ 7.3 Definitions.

(a) "Agency" means the Food and Drug Administration.

(b) "Citation" or "cite" means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) "Respondent" means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) "Responsible individual" includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) "Product" means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under Part 1240 of this chapter. "Product" does not include an electronic product that emits radiation and is subject to Parts 1003 and 1004 of this chapter.

(g) "Recall" means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. "Recall" does not include a market withdrawal or a stock recovery.

(h) "Correction" means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

(i) "Recalling firm" means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

(j) "Market withdrawal" means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

(k) "Stock recovery" means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.

(l) "Recall strategy" means a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

(m) "Recall classification" means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

(1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

(2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

(3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

(n) "Consignee" means anyone who received, purchased, or used the product being recalled.

(Sec. 1 et seq., Pub. L. 717, 52 Stat. 1040–1059 as amended (21 U.S.C. 301 et seq.); secs. 301, 351, and 361, Pub. L. 410, 58 Stat. 691–703 as amended (42 U.S.C. 241, 262, and 264); secs. 305, 701(a) (21 U.S.C. 335, 371(a)))

[42 FR 15567, Mar. 22, 1977, as amended at 43 FR 26218, June 16, 1978; 44 FR 12167, Mar. 6, 1979]

§ 7.12 Guaranty.

In case of the giving of a guaranty or undertaking referred to in section 303(c)(2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

(Sec. 301, 52 Stat. 1042, as amended; 21 U.S.C. 331)

§ 7.13 Suggested forms of guaranty.

(a) A guaranty or undertaking referred to in section 303(c)(2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303(c)(2) of the act:

(1) Limited form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking.)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or in the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking.)

(c) The application of a guaranty or undertaking referred to in section 303(c)(2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404, 505, or 512 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303(c)(3) of the act shall state that the shipment or other delivery of the color additive covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303(c)(3) of the act:

(1) For domestic manufacturers:

(Name of manufacturer) hereby guarantees that all color additives listed herein were manufactured by him, and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(2) For foreign manufacturers:

(Name of manufacturer and agent) hereby severally guarantee that all color additives listed herein were manufactured by (name of manufacturer), and (where color additive regulations require certification) are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer.)

(Signature and post-office address of agent.)

(f) For the purpose of a guaranty or undertaking under section 303(c)(3) of the act the manufacturer of a shipment or other delivery of a color additive is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

(Sec. 303, 52 Stat. 1043; 21 U.S.C. 333)

Subpart B—[Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidelines on Policy, Procedures, and Industry Responsibilities

AUTHORITY: Sec. 1 et seq., Pub. L. 717, 52 Stat. 1040-1059 as amended (21 U.S.C. 301 et seq.); secs. 301, 351, and 361, Pub. L. 410, 58 Stat. 691-703 as amended (42 U.S.C. 241, 262, and 264).

SOURCE: 43 FR 26218, June 16, 1978, unless otherwise noted.

§ 7.40 Recall policy.

(a) Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidelines so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall.

(b) Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufacture and marketing of the product that is to be recalled.

(c) Recall is generally more appropriate and affords better protection for consumers than seizure, when many lots of product have been widely distributed. Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the Food and Drug Administration, or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing.

§ 7.41 Health hazard evaluation and recall classification.

(a) An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug Administration scientists and will take into account, but need not be limited to, the following factors:

(1) Whether any disease or injuries have already occurred from the use of the product.

(2) Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.

(3) Assessment of hazard to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.

(4) Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.

(5) Assessment of the likelihood of occurrence of the hazard.

(6) Assessment of the consequences (immediate or long-range) of occurrence of the hazard.

(b) On the basis of this determination, the Food and Drug Administration will assign the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall.

§ 7.42 Recall strategy.

(a) *General.* (1) A recall strategy that takes into account the following factors will be developed by the agency for a Food and Drug Administration-requested recall and by the recalling firm for a firm-initiated recall to suit the individual circumstances of the particular recall:

(i) Results of health hazard evaluation.

(ii) Ease in identifying the product.

(iii) Degree to which the product's deficiency is obvious to the consumer or user.

(iv) Degree to which the product remains unused in the market-place.

(v) Continued availability of essential products.

(2) The Food and Drug Administration will review the adequacy of a proposed recall strategy developed by a recalling firm and recommend changes as appropriate. A recalling firm should conduct the recall in accordance with an approved recall strategy but need not delay initiation of a recall pending review of its recall strategy.

(b) *Elements of a recall strategy.* A recall strategy will address the following elements regarding the conduct of the recall:

(1) *Depth of recall.* Depending on the product's degree of hazard and extent of distribution, the recall strategy will specify the level in the distribution chain to which the recall is to extend, as follows:

(i) Consumer or user level, which may vary with product, including any intermediate wholesale or retail level; or

(ii) Retail level, including any intermediate wholesale level; or

(iii) Wholesale level.

(2) *Public warning.* The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. It is reserved for urgent situations where other means for preventing use of the recalled product appear inadequate. The Food and Drug Administration in consultation with the recalling firm will ordinarily issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning for review and comment by the Food and Drug Administration. The recall strategy will specify whether a public warning is needed and whether it will issue as:

(i) General public warning through the general news media, either national or local as appropriate, or

(ii) Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals, etc.

(3) *Effectiveness checks.* The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

(i) Level A—100 percent of the total number of consignees to be contacted;

(ii) Level B—Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater that 10 percent and less than 100 percent of the total number of consignees;

(iii) Level C—10 percent of the total number of consignees to be contacted;

(iv) Level D—2 percent of the total number of consignees to be contacted; or

(v) Level E—No effectiveness checks.

[43 FR 26218, June 16, 1978, as amended at 46 FR 8455, Jan. 27, 1981]

§ 7.45 Food and Drug Administration-requested recall.

(a) The Commissioner of Food and Drugs or his designee under § 5.20 of this chapter may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception.

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare.

(b) The Commissioner or his designee will notify the firm of this determination and of the need to begin immediately a recall of the product. Such notification will be by letter or telegram to a responsible official of the firm, but may be preceded by oral communication or by a visit from an authorized representative of the local Food and Drug Administration district office, with formal, written confirmation from the Commissioner or his designee afterward. The notification will specify the violation, the health hazard classification of the violative product, the recall strategy, and other appropriate instructions for conducting the recall.

(c) Upon receipt of a request to recall, the firm may be asked to provide the Food and Drug Administration any or all of the information listed in § 7.46(a). The firm, upon agreeing to the recall request, may also provide other information relevant to the agency's determination of the need for the recall or how the recall should be conducted.

§ 7.46 Firm-initiated recall.

(a) A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. A firm that does so because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter. Such removal or correction will be considered a recall only if the Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases, the firm will be asked to provide the Food and Drug Administration the following information:

(1) Identity of the product involved.

(2) Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.

(3) Evaluation of the risk associated with the deficiency or possible deficiency.

(4) Total amount of such products produced and/or the timespan of the production.

(5) Total amount of such products estimated to be in distribution channels.

(6) Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.

(7) A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.

(8) Proposed strategy for conducting the recall.

(9) Name and telephone number of the firm official who should be contacted concerning the recall.

(b) The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.

(c) A firm may decide to recall a product when informed by the Food and Drug Administration that the agency has determined that the product in question violates the law, but the agency has not specifically requested a recall. The firm's action also is considered a firm-initiated recall and is subject to paragraphs (a) and (b) of this section.

(d) A firm that initiates a removal or correction of its product which the firm believes is a market withdrawal should consult with the appropriate Food and Drug Administration district office when the reason for the removal or correction is not obvious or clearly understood but where it is apparent, e.g., because of complaints or adverse reactions regarding the product, that the product is deficient in some respect. In such cases, the Food and Drug Administration will assist the firm in determining the exact nature of the problem.

§ 7.49 Recall communications.

(a) *General.* A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:

(1) That the product in question is subject to a recall.

(2) That further distribution or use of any remaining product should cease immediately.

(3) Where appropriate, that the direct account should in turn notify its

customers who received the product about the recall.

(4) Instructions regarding what to do with the product.

(b) *Implementation.* A recall communication can be accomplished by telegrams, mailgrams, or first class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "DRUG [or FOOD, BIOLOGIC, etc.] RECALL [or CORRECTION]". The letter and the envelope should be also marked: "URGENT" for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.

(c) *Contents.* (1) A recall communication should be written in accordance with the following guidelines:

(i) Be brief and to the point;

(ii) Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product;

(iii) Explain concisely the reason for the recall and the hazard involved, if any;

(iv) Provide specific instructions on what should be done with respect to the recalled products; and

(v) Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.

(2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, followup communications should be sent to those who fail to respond to the initial recall communication.

(d) *Responsibility of recipient.* Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

§ 7.50 Public notification of recall.

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were effected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

§ 7.53 Recall status reports.

(a) The recalling firm is requested to submit periodic recall status reports to the appropriate Food and Drug Administration district office so that the agency may assess the progress of the recall. The frequency of such reports will be determined by the relative urgency of the recall and will be specified by the Food and Drug Administration in each recall case; generally the reporting interval will be between 2 and 4 weeks.

(b) Unless otherwise specified or inappropriate in a given recall case, the recall status report should contain the following information:

(1) Number of consignees notified of the recall, and date and method of notification.

(2) Number of consignees responding to the recall communication and quatity of products on hand at the time it was received.

(3) Number of consignees that did not respond (if needed, the identity of

nonresponding consignees may be requested by the Food and Drug Administration).

(4) Number of products returned or corrected by each consignee contacted and the quantity of products accounted for.

(5) Number and results of effectiveness checks that were made.

(6) Estimated time frames for completion of the recall.

(c) Recall status reports are to be discontinued when the recall is terminated by the Food and Drug Administration.

§ 7.55 Termination of a recall.

(a) A recall will be terminated when the Food and Drug Administration determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. Written notification that a recall is terminated will be issued by the appropriate Food and Drug Administration district office to the recalling firm.

(b) A recalling firm may request termination of its recall by submitting a written request to the appropriate Food and Drug Adminstration district office stating that the recall is effective in accordance with the criteria set forth in paragraph (a) of this section, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

§ 7.59 General industry guidance.

A recall can be disruptive of a firm's operation and business, but there are several steps a prudent firm can take in advance to minimize this disruptive effect. Notwithstanding similar specific requirements for certain products in other parts of this chapter, the following is provided by the Food and Drug Administration as guidance for a firm's consideration:

(a) Prepare and maintain a current written contingency plan for use in initiating and effecting a recall in accordance with §§ 7.40 through 7.49, 7.53, and 7.55.

(b) Use sufficient coding of regulated products to make possible positive lot identification and to facilitate effective recall of all violative lots.

(c) Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.

Subpart D—[Reserved]

Subpart E—Criminal Violations

§ 7.84 Opportunity for presentation of views before report of criminal violation.

(a)(1) Except as provided in paragraph (a)(2) and (3) of this section, a person against whom criminal prosecution under the Federal Food, Drug, and Cosmetic Act is contemplated by the Commissioner of Food and Drugs shall be given appropriate notice and an opportunity to present information and views to show cause why criminal prosecution should not be recommended to a United States attorney.

(2) Notice and opportunity need not be provided if the Commissioner has reason to believe that they may result in the alteration or destruction of evidence or in the prospective defendant's fleeing to avoid prosecution.

(3) Notice and opportunity need not be provided if the Commissioner contemplates recommending further investigation by the Department of Justice.

(b) If a statute enforced by the Commissioner does not contain a provision for an opportunity to present views, the Commissioner need not, but may in the Commissioner's discretion, provide notice and an opportunity to present views.

(c) If an apparent violation of the Federal Food, Drug, and Cosmetic Act also constitutes a violation of any other Federal statute(s), and the Commissioner contemplates recommending prosecution under such other statute(s) as well, the notice of opportunity to present views will include all violations.

(d) Notice of an opportunity to present views may be by letter, standard form, or other document(s) identifying the products and/or conduct alleged to violate the law. The notice shall—

(1) Be sent by registered or certified mail, telegram, telex, personal delivery, or any other appropriate mode of written communication;

(2) Specify the time and place where those named may present their views;

(3) Summarize the violations that constitute the basis of the contemplated prosecution;

(4) Describe the purpose and procedure of the presentation; and

(5) Furnish a form on which the legal status of any person named in the notice may be designated.

(e) If more than one person is named in a notice, a separate opportunity for presentation of views shall be scheduled on request. Otherwise, the time and place specified in a notice may be changed only upon a showing of reasonable grounds. A request for any change shall be addressed to the Food and Drug Administration office that issued the notice and shall be received in that office at least 3 working days before the date set in the notice.

(f) A person who has received a notice is under no legal obligation to appear or answer in any manner. A person choosing to respond may appear personally, with or without a representative, or may designate a representative to appear for him or her. Alternatively, a person may respond in writing. If a person elects not to respond on or before the time scheduled, the Commissioner will, without further notice, decide whether to recommend criminal prosecution to a United States attorney on the basis of the information available.

(g) If a respondent chooses to appear solely by designated representative, that representative shall present a signed statement of authorization. If a representative appears for more than one respondent, the representative shall submit independent documentation of authority to act for each respondent. If a representative appears without written authorization, the opportunity to present views with respect to that respondent may be provided at that time only if the authenticity of the representative's authority is first verified by telephone or other appropriate means.

(Secs. 305, 701(a), 52 Stat. 1045, 1055 (21 U.S.C. 335, 371(a)))

[44 FR 12167, Mar. 6, 1979]

§ 7.85 Conduct of a presentation of views before report of criminal violation.

(a) The presentation of views shall be heard by a designated Food and Drug Administration employee. Other Food and Drug Administration employees may be present.

(b) A presentation of views shall not be open to the public. The agency employee designated to receive views will permit participation of other persons only if they appear with the respondent or the respondent's designated representative, and at the request of, and on behalf of, the respondent.

(c) A respondent may present any information of any kind bearing on the Commissioner's determination to recommend prosecution. Information may include statements of persons appearing on the respondent's behalf, letters, documents, laboratory analyses, if applicable, or other relevant information or arguments. The opportunity to present views shall be informal. The rules of evidence shall not apply. Any information given by a respondent, including statements by the respondent, shall become part of the agency's records concerning the matter and may be used for any official purpose. The Food and Drug Administration is under no obligation to present evidence or witnesses.

(d) If the respondent holds a "guaranty or undertaking" as described in section 303(c) of the act (21 U.S.C. 333(c)) that is applicable to the notice, that document, or a verified copy of it, may be presented by the respondent.

(e) A respondent may have an oral presentation recorded and transcribed at his or her expense, in which case a copy of the transcription shall be furnished to the Food and Drug Administration office from which the notice issued. The employee designated to receive views may order a presentation of views recorded and transcribed at agency expense, in which case a copy of such transcription shall be provided to each respondent.

(f) If an oral presentation is not recorded and transcribed, the agency employee designated to receive views shall dictate a written summary of the presentation. A copy of the summary shall be provided to each respondent.

(g) A respondent may comment on the summary or may supplement any response by additional written or documentary evidence. Any comment or addition shall be furnished to the Food and Drug Administration office where the respondent's views were presented. If materials are submitted within 10 calendar days after receipt of the copy of the summary or transcription of the presentation, as applicable, they will be considered before a final decision as to whether or not to recommend prosecution. Any materials received after the supplemental response period generally will be considered only if the final agency decision has not yet been made.

(h)(1) When consideration of a criminal prosecution recommendation involving the same violations is closed by the Commissioner with respect to all persons named in the notice, the Commissioner will so notify each person in writing.

(2) When it is determined that a person named in a notice will not be included in the Commissioner's recommendation for criminal prosecution, the Commissioner will so notify that person, if and when the Commissioner concludes that notification will not prejudice the prosecution of any other person.

(3) When a United States attorney informs the agency that no persons recommended will be prosecuted, the Commissioner will so notify each person in writing, unless the United States attorney has already done so.

(4) When a United States attorney informs the agency of intent to prosecute some, but not all, persons who had been provided an opportunity to present views and were subsequently named in the Commissioner's recommendation for criminal prosecution, the Commissioner, after being advised by the United States attorney that the notification will not prejudice the prosecution of any other person, will so notify those persons eliminated from further consideration, unless the United States attorney has already done so.

(Secs. 305, 701(a), 52 Stat. 1045, 1055 (21 U.S.C. 335, 371(a)))

[44 FR 12168, Mar. 6, 1979]

§ 7.87 Records related to opportunities for presentation of views conducted before report of criminal violation.

(a) Records related to a section 305 opportunity for presentation of views constitute investigatory records for law enforcement purposes and may include inter- and intra-agency memorandums.

(1) Notwithstanding the rule established in § 20.21 of this chapter, no record related to a section 305 presentation is available for public disclosure until consideration of criminal prosecution has been closed in accordance with paragraph (b) of this section, except as provided in § 20.82 of this chapter. Only very rarely and only under circumstances that demonstrate a compelling public interest will the Commissioner exercise, in accordance with § 20.82 of this chapter, the authorized discretion to disclose records related to a section 305 presentation before the consideration of criminal prosecution is closed.

(2) After consideration of criminal prosecution is closed, the records are available for public disclosure in response to a request under the Freedom of Information Act, except to the extent that the exemptions from disclosure in Subpart D of Part 20 of this chapter are applicable. No statements obtained through promises of confidentiality shall be available for public disclosure.

(b) Consideration of criminal prosecution based on a particular section 305 notice of opportunity for presentation of views shall be deemed to be closed within the meaning of this section and § 7.85 when a final decision has been made not to recommend criminal prosecution to a United States attorney based on charges set forth in the notice and considered at the presentation, or when such a recommendation has been finally refused by the United States attorney, or when criminal prosecution has been instituted and the matter and all related appeals have been concluded, or when the statute of limitations has run.

(c) Before disclosure of any record specifically reflecting consideration of a possible recommendation for criminal prosecution of any individual, all names and other information that would identify an individual whose prosecution was considered but not recommended, or who was not prosecuted, shall be deleted, unless the Commissioner concludes that there is a compelling public interest in the disclosure of the names.

(d) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records related to a section 305 presentation of views before public disclosure only under § 20.32 of this chapter.

(Secs. 305, 701(a), 52 Stat. 1045, 1055 (21 U.S.C. 335, 371(a)))

[44 FR 12168, Mar. 6, 1979]

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

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Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

10.200 Scope.
10.203 Definitions.
10.204 General.
10.205 Electronic media coverage of public administrative proceedings.
10.206 Procedures for electronic media coverage of agency public administrative proceedings.

AUTHORITY: Sec. 201 *et seq.*, Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 *et seq.*); sec. 1 *et seq.*, Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 *et seq.*); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 *et seq.*, Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 *et seq.*); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 *et seq.*, Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 *et seq.*); secs. 1-9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1-10, Ch. 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 *et seq.*, Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 *et seq.*); sec. 1 *et seq.*, Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 *et seq.*); Pub. L. 100-236, 101 Stat. 1731 (28 U.S.C. 2112).

SOURCE: 44 FR 22323, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 10.1 Scope.

(a) Part 10 governs practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food Drug, and Cosmetic Act, the Public Health Service Act, and other laws that the Commissioner of Food and Drugs administers under § 5.10.

(b) If a requirement in another part of Title 21 differs from a requirement in this part, the requirements of this part apply to the extent that they do not conflict with the other requirements.

(c) References in this part and Parts 12, 13, 14, 15, and 16 to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

(d) References in this part and Parts 12, 13, 14, 15, and 16 to "publication," or to the day or date of publication, or use of the phrase "to publish," refer to publication in the FEDERAL REGISTER unless otherwise noted.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989]

§ 10.3 Definitions.

(a) The following definitions apply in this part and Parts 12, 13, 14, 15, 16, and 19:

"Act" means the Federal Food, Drug, and Cosmetic Act unless otherwise indicated.

"Administrative action" includes every act, including the refusal or failure to act, involved in the administration of any law by the Commissioner, except that it does not include the referral of apparent violations to U.S. attorneys for the institution of civil or criminal proceedings or an act in preparation of a referral.

"Administrative file" means the file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations.

"Administrative record" means the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action.

"Agency" means the Food and Drug Administration.

"Chief Counsel" means the Chief Counsel of the Food and Drug Administration.

"Commissioner" means the Commissioner of Food and Drugs, Food and Drug Administration, U.S. Department of Health and Human Services, or the Commissioner's designee.

"Department" means the U.S. Department of Health and Human Services.

"Dockets Management Branch" means the Dockets Management Branch, Office of Management and Operations of the Food and Drug Administration, U.S. Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

"Ex parte communication" means an oral or written communication not on the public record for which reasonable prior notice to all parties is not given, but does not include requests for status reports on a matter.

"FDA" means the Food and Drug Administration.

"Food and Drug Administration employee" or "Food and Drug Administration representative" includes members of the Food and Drug Division of the office of the General Counsel of the Department of Health and Human Services.

"Formal evidentiary public hearing" means a hearing conducted under part 12.

"Interested person" or "any person who will be adversely affected" means a person who submits a petition or comment or objection or otherwise asks to participate in an informal or formal administrative proceeding or court action.

"Meeting" means any oral discussion, whether by telephone or in person.

"Office of the Commissioner" includes the offices of the Associate Commissioners but not the centers or the regional or district offices.

"Order" means the final agency disposition, other than the issuance of a regulation, in a proceeding concerning any matter and includes action on a new drug application, new animal drug application, or biological license.

"Participant" means any person participating in any proceeding, including each party and any other interested person.

"Party" means the center of the Food and Drug Administration responsible for a matter involved and every person who either has exercised a right to request or has been granted the right by the Commissioner to have a hearing under Part 12 or Part 16 or who has waived the right to a hearing to obtain the establishment of a Public Board of Inquiry under Part 13 and as a result of whose action a hearing or a Public Board of Inquiry has been established.

"Person" includes an individual, partnership, corporation, association, or other legal entity.

"Petition" means a petition, application, or other document requesting the Commissioner to establish, amend, or revoke a regulation or order, or to take or not to take any other form of administrative action, under the laws administered by the Food and Drug Administration.

"Presiding officer" means the Commissioner or the Commissioner's designee or an administrative law judge appointed as provided in 5 U.S.C. 3105.

"Proceeding" and "administrative proceeding" means any undertaking to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

"Public advisory committee" or "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup of an advisory committee, that is not composed wholly of full-time employees of the Federal Government and is established or utilized by the Food and Drug Administration to obtain advice or recommendations.

"Public Board of Inquiry" or "Board" means an administrative law tribunal constituted under Part 13.

"Public hearing before a public advisory committee" means a hearing conducted under Part 14.

"Public hearing before a Public Board of Inquiry" means a hearing conducted under Part 13.

"Public hearing before the Commissioner" means a hearing conducted under Part 15.

"Regulations" means an agency rule of general or particular applicability and future effect issued under a law administered by the Commissioner or relating to administrative practices and procedures. In accordance with § 10.90(a), each agency regulation will be published in the FEDERAL REGISTER and codified in the Code of Federal Regulations.

"Regulatory hearing before the Food and Drug Administration" means a hearing conducted under Part 16.

"Secretary" means the Secretary of Health and Human Services.

"The laws administered by the Commissioner" or "the laws administered by the Food and Drug Administration" means all the laws that the Commissioner is authorized to administer under § 5.10.

(b) A term that is defined in section 201 of the Federal Food, Drug, and Cosmetic Act or Part 1 has the same definition in this part.

(c) Words in the singular form include the plural, words in the masculine form include the feminine, and vice versa.

(d) Whenever a reference is made in this part to a person in FDA, e.g., the director of a center, the reference includes all persons to whom that person has delegated the specific function involved.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 FR 8994, Mar. 6, 1985; 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989]

§ 10.10 Summaries of administrative practices and procedures.

To encourage public participation in all agency activities, the Commissioner will prepare for public distribution summaries of FDA administrative practices and procedures in readily understandable terms.

§ 10.19 Waiver, suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the request of a participant, waive, suspend, or modify any provision in Parts 12 through 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law.

Subpart B—General Administrative Procedures

§ 10.20 Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure.

(a) A submission to the Dockets Management Branch of a petition, comment, objection, notice, compilation of information, or any other document is to be filed in four copies except as otherwise specifically provided in a relevant FEDERAL REGISTER notice or in another section of this chapter. The Dockets Management Branch is the agency custodian of these documents.

(b) A submission is to be signed by the person making it, or by an attorney or other authorized representative of that person. Submissions by trade associations are also subject to the requirements of § 10.105(b).

(c) Information referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.

(1) A copy of an article or other reference or source cited must be included, except where the reference or source is:

(i) A reported Federal court case;

(ii) A Federal law or regulation;

(iii) An FDA document that is routinely publicly available;

(iv) A recognized medical or scientific textbook that is readily available to the agency; or

(v) A designated journal listed in § 510.95.

(2) If a part of the material submitted is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. A translation of literature or other material in a foreign language is to be accompanied by copies of the original publication.

(3) Where relevant information is contained in a document also containing irrelevant information, the irrelevant information is to be deleted and only the relevant information is to be submitted.

(4) Under § 20.63 (a) and (b), the names and other information that would identify patients or research subjects are to be deleted from any record before it is submitted to the Dockets Management Branch in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter is to be deleted from a record before it is submitted to the Dockets Management Branch.

(6) The failure to comply with the requirements of this part or with § 12.80 or § 13.20 will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply. If a submission fails to meet any requirement of this section and the deficiency becomes known to the Dockets Management Branch, the Dockets Management Branch shall not file the submission but return it with a copy of the applicable regulations indicating those provisions not complied with. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Dockets Management Branch does not make decisions regarding the confidentiality of submitted documents. Persons wishing to voluntarily submit information considered confidential shall follow the presubmission review requirements of § 20.44.

(d) The filing of a submission means only that the Dockets Management Branch has identified no technical deficiencies in the submission. The filing of a petition does not mean or imply that it meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) All submissions to the Dockets Management Branch will be considered as submitted on the date they are postmarked or, if delivered in person during regular business hours, on the date they are delivered, unless a provision in this part, an applicable FEDERAL REGISTER notice, or an order issued by an administrative law judge specifically states that the documents must be received by a specified date, e.g., § 10.33(g) relating to a petition for reconsideration, in which case they will be considered submitted on the date received.

(f) All submissions are to be mailed or delivered in person to the Dockets Management Branch, Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857, except that a submission which is required to be received by the Branch by a specified date may be delivered in person to the FDA building in Washington (Room 6819, 200 C Street SW., Washington, DC 20204) and will be considered as received by the Branch on the date on which it is delivered.

(g) FDA ordinarily will not acknowledge or give receipt for documents, except:

(1) Documents delivered in person or by certified or registered mail with a return receipt requested; and

(2) Petitions for which acknowledgment of receipt of filing is provided by regulation or by customary practice, e.g., § 10.30(c) relating to a citizen petition.

(h) Saturdays, Sundays, and Federal legal holidays are included in computing the time allowed for the submission of documents, except that when the time for submission expires on a Saturday, Sunday, or Federal legal holiday, the period will be extended to include the next business day.

(i) All submissions to the Dockets Management Branch are representations that, to the best of the knowledge, information, and belief of the person making the submission, the statements made in the submission are true and accurate. All submissions are subject to the False Reports to the Government Act (18 U.S.C. 1001) under which a willfully false statement is a criminal offense.

(j) The availability for public examination and copying of submissions to the Dockets Management Branch is governed by the following rules:

(1) Except to the extent provided in paragraphs (j)(2) and (3) of this section, the following submissions, including all supporting material, will be on public display and will be available for public examination between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of submissions will be filed and handled in accordance with Subpart C of Part 20:

(i) Petitions.

(ii) Comments on petitions, on documents published in the FEDERAL REGISTER, and on similar public documents.

(iii) Objections and requests for hearings filed under Part 12.

(iv) Material submitted at a hearing under § 12.32(a)(2) and Parts 12, 13, and 15.

(v) Material placed on public display under the regulations in this chapter, e.g., agency guidelines filed under § 10.90(b).

(2)(i) Material prohibited from public disclosure under § 20.63 (clearly unwarranted invasion of personal privacy) and, except as provided in paragraph (j)(3) of this section, material submitted with objections and requests for hearing filed under Part 12, or at a hearing under Part 12 or Part 13, or an alternative form of public hearing before a public advisory committee or a hearing under § 12.32(a)(2) or (3), of the following types will not be on public display, will not be available for public examination, and will not be available for copying or any other form of verbatim transcription unless it is otherwise available for public disclosure under Part 20:

(*a*) Safety and effectiveness information, which includes all studies and tests of an ingredient or product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

(*b*) A protocol for a test or study.

(*c*) Manufacturing methods or processes, including quality control procedures.

(*d*) Production, sales distribution, and similar information, except any compilation of information aggregated and prepared in a way that does not reveal confidential information.

(*e*) Quantitative or semiquantitative formulas.

(*f*) Information on product design or construction.

(ii) Material submitted under paragraph (j)(2) of this section is to be segregated from all other submitted material and clearly so marked. A person who does not agree that a submission is properly subject to paragraph (j)(2) may request a ruling from the Associate Commissioner for Public Affairs whose decision is final, subject to judicial review under § 20.46.

(3) Material listed in paragraph (j)(2)(i) (*a*) and (*b*) of this section may be disclosed under a protective order issued by the administrative law judge or other presiding officer at a hearing referenced in paragraph (j)(2)(i). The administrative law judge or presiding officer shall permit disclosure of the data only in camera and only to the extent necessary for the proper conduct of the hearing. The administrative law judge or presiding officer shall direct to whom the information is to be made available (e.g., to parties or participants, or only to counsel for parties or participants), and persons not specifically permitted access to the data will be excluded from the in camera part of the proceeding. The administrative law judge or other presiding officer may impose other conditions or safeguards. The limited availability of material under this paragraph does not constitute prior disclosure to the public as defined in § 20.81, and no information subject to a particular order is to be submitted to or received or considered by FDA in support of a petition or other request from any other person.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 49 FR 7363, Feb. 29, 1984; 54 FR 9034, Mar. 3, 1989]

§ 10.25 Initiation of administrative proceedings.

An administrative proceeding may be initiated in the following three ways:

(a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either: (1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.50, for a new animal drug application in § 514.1, or (2) in the form for a citizen petition in § 10.30.

(b) The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.

(c) The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989]

§ 10.30 Citizen petition.

(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter.

(b) A petition (including any attachments) must be submitted in accordance with § 10.20 and in the following form:

(Date) ______________________

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

CITIZEN PETITION

The undersigned submits this petition under —— (relevant statutory sections, if known) of the —— (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to —— (issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action).

A. Action requested

((1) If the petition requests the Commissioner to issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests the Commissioner to issue, amend, or revoke an order, a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.)

((3) If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, the specific action or relief requested.)

B. Statement of grounds

(A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position.)

C. Environmental impact

(A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) ————————
(Name of petitioner) ————————
(Mailing address) ————————
(Telephone number) ————————

(c) A petition which appears to meet the requirements of paragraph (b) of this section and § 10.20 will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Dockets Management Branch for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. Related petitions may be filed together and given the same docket number. The Dockets Management Branch will promptly notify the petitioner in writing of the filing and docket number of a petition.

(d) An interested person may submit written comments to the Dockets Management Branch on a filed petition, which comments become part of the docket file. The comments are to specify the docket number of the petition and may support or oppose the petition in whole or in part. A request for alternative or different administrative action must be submitted as a separate petition.

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute.

(2) The Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

(i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a Federal Register notice) implementing the approval;

(ii) Deny the petition; or

(iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

(3) The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. The petitioner is to be notified in writing of the Commissioner's decision. The decision will be placed in the public docket file in the office of the Dockets Management Branch and may also be in the form of a notice published in the Federal Register.

(f) If a petition filed under paragraph (c) of this section requests the Commissioner to issue, amend, or revoke a regulation, § 10.40 or § 10.50 also apply.

(g) A petitioner may supplement, amend, or withdraw a petition in writing without agency approval and without prejudice to resubmission at anytime until the Commissioner rules on the petition, unless the petition has been referred for a hearing under Parts 12, 13, 14, or 15. After a ruling or referral, a petition may be supplemented, amended, or withdrawn only with the approval of the Commissioner. The Commissioner may approve withdrawal, with or without prejudice against resubmission of the petition.

(h) In reviewing a petition the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, 15, or 16.

(3) A Federal Register notice requesting information and views.

(4) A proposal to issue, amend, or revoke a regulation, in accordance with § 10.40 or § 12.20.

(5) Any other specific public procedure established in this chapter and expressly applicable to the matter.

(i) The record of the administrative proceeding consists of the following:

(1) The petition, including all information on which it relies, filed by the Dockets Management Branch.

(2) All comments received on the petition, including all information submitted as a part of the comments.

(3) If the petition resulted in a proposal to issue, amend, or revoke a regulation, all of the documents specified in § 10.40(g).

(4) The record, consisting of any transcripts, minutes of meetings, reports, Federal Register notices, and other documents resulting from the optional procedures specified in paragraph (h) of this section, except a transcript of a closed portion of a public advisory committee meeting.

(5) The Commissioner's decision on the petition, including all information identified or filed by the Commissioner with the Dockets Management Branch as part of the record supporting the decision.

(6) All documents filed with the Dockets Management Branch under § 10.65(h).

(7) If a petition for reconsideration or for a stay of action is filed under paragraph (j) of this section, the administrative record specified in § 10.33(k) or § 10.35(h).

(j) The administrative record specified in paragraph (i) of this section is the exclusive record for the Commissioner's decision. The record of the administrative proceeding closes on the date of the Commissioner's decision unless some other date is specified. Thereafter any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the decision in accordance with this section.

(k) This section does not apply to the referral of a matter to a United States attorney for the initiation of court enforcement action and related correspondence, or to requests, suggestions, and recommendations made informally in routine correspondence received by FDA. Routine correspondence does not constitute a petition within the meaning of this section unless it purports to meet the requirements of this section. Action on routine correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(l) The Dockets Management Branch will maintain a chronological list of each petition filed under this section and § 10.85, but not of petitions submitted elsewhere in the agency under § 10.25(a)(1), showing:

(1) The docket number;

(2) The date the petition was filed by the Dockets Management Branch;

(3) The name of the petitioner;

(4) The subject matter involved; and

(5) The disposition of the petition.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 50 16656, Apr. 26, 1985; 54 FR 9034, Mar. 3, 1989]

§ 10.33 Administrative reconsideration of action.

(a) The Commissioner may at any time reconsider a matter, on the Commissioner's own initiative or on the petition of an interested person.

(b) An interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under § 10.25. Each request for reconsideration must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the FEDERAL REGISTER, the day of publication is the day of decision.

(Date) ____________

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

PETITION FOR RECONSIDERATION

[Docket No.]

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in Docket No. ———.

A. Decision involved

(A concise statement of the decision of the Commissioner which the petitioner wishes to have reconsidered.)

B. Action requested

(The decision which the petitioner requests the Commissioner to make upon reconsideration of the matter.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner.

(No new information or views may be included in a petition for reconsideration.)

(Signature) ____________
(Name of petitioner) ____________
(Mailing address) ____________
(Telephone number) ____________

(c) A petition for reconsideration relating to a petition submitted under § 10.25(a)(2) is subject to the requirements of § 10.30 (c) and (d), except that it is filed in the same docket file as the petition to which it relates.

(d) The Commissioner shall promptly review a petition for reconsideration. The Commissioner may grant the petition when the Commissioner determines it is in the public interest and in the interest of justice. The Commissioner shall grant a petition for reconsideration in any proceeding if the Commissioner determines all of the following apply:

(1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.

(2) The petitioner's position is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.

(4) Reconsideration is not outweighed by public health or other public interests.

(e) A petition for reconsideration may not be based on information and views not contained in the administrative record on which the decision was made. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision under § 10.25(a).

(f) The decision on a petition for reconsideration is to be in writing and placed on public display as part of the docket file on the matter in the office of the Dockets Management Branch. A determination to grant reconsideration will be published in the FEDERAL REGISTER if the Commissioner's original decision was so published. Any other determination to grant or deny reconsideration may also be published in the FEDERAL REGISTER.

(g) The Commissioner may consider a petition for reconsideration only before the petitioner brings legal action in the courts to review the action, except that a petition may also be considered if the Commissioner has denied a petition for stay of action and the petitioner has petitioned for judicial review of the Commissioner's action and requested the reviewing court to grant a stay pending consideration of review. A petition for reconsideration submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for reconsideration will be considered as submitted on the day it is received by the Dockets Management Branch.

(h) The Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken. If review of the matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding is to include all additional documents relating to such reconsideration.

(i) After determining to reconsider a matter, the Commissioner shall review and rule on the merits of the matter under § 10.30(e). The Commissioner may reaffirm, modify, or overrule the prior decision, in whole or in part, and may grant such other relief or take such other action as is warranted.

(j) The Commissioner's reconsideration of a matter relating to a petition submitted under § 10.25(a)(2) is subject to § 10.30 (f) through (h), (j), and (k).

(k) The record of the administrative proceeding consists of the following:

(1) The record of the original petition specified in § 10.30(i).

(2) The petition for reconsideration, including all information on which it relies, filed by the Dockets Management Branch.

(3) All comments received on the petition, including all information submitted as a part of the comments.

(4) The Commissioner's decision on the petition under paragraph (f) of this section, including all information identified or filed by the Commissioner with the Dockets Management Branch as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from the petition.

(6) All documents filed with the Dockets Management Branch under § 10.65(h).

(7) If the Commissioner reconsiders the matter, the administrative record relating to reconsideration specified in § 10.30(i).

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981]

§ 10.35 Administrative stay of action.

(a) The Commissioner may at any time stay or extend the effective date of an action pending or following a decision on any matter.

(b) An interested person may request the Commissioner to stay the effective date of any administrative action. A stay may be requested for a specific time period or for an indefinite time period. A request for stay must be submitted in accordance with § 10.20 and in the following form no later than 30 days after the date of the decision involved. The Commissioner may, for good cause, permit a petition to be filed after 30 days. In the case of a decision published in the FEDERAL REGISTER, the day of publication is the date of decision.

(Date) ______________________

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

PETITION FOR STAY OF ACTION

The undersigned submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following matter.

A. Decision involved

(The specific administrative action being taken by the Commissioner for which a stay is requested, including the docket number or other citation to the action involved.)

B. Action requested

(The length of time for which the stay is requested, which may be for a specific or indefinite time period.)

C. Statement of grounds

(A full statement, in a well-organized format, of the factual and legal grounds upon which the petitioner relies for the stay.)

(Signature) ______________________
(Name of petitioner) ______________________
(Mailing address) ______________________
(Telephone number) ______________________

(c) A petition for stay of action relating to a petition submitted under § 10.25(a)(2) is subject to the requirements of § 10.30 (c) and (d), except that it will be filed in the same docket file as the petition to which it relates.

(d) Neither the filing of a petition for a stay of action nor action taken by an interested person in accordance with any other administrative procedure in this part or in any other section of this chapter, e.g., the filing of a citizen petition under § 10.30 or a petition for reconsideration under § 10.33 or a request for an advisory opinion under § 10.85, will stay or otherwise delay any administrative action by the Commissioner, including enforcement action of any kind, unless one of the following applies:

(1) The Commissioner determines that a stay or delay is in the public interest and stays the action.

(2) A statute requires that the matter be stayed.

(3) A court orders that the matter be stayed.

(e) The Commissioner shall promptly review a petition for stay of action. The Commissioner may grant or deny a petition, in whole or in part; and may grant such other relief or take such other action as is warranted by the petition. The Commissioner may grant a stay in any proceeding if it is in the public interest and in the interest of justice. The Commissioner shall grant a stay in any proceeding if all of the following apply:

(1) The petitioner will otherwise suffer irreparable injury.

(2) The petitioner's case is not frivolous and is being pursued in good faith.

(3) The petitioner has demonstrated sound public policy grounds supporting the stay.

(4) The delay resulting from the stay is not outweighted by public health or other public interests.

(f) The Commissioner's decision on a petition for stay of action is to be in writing and placed on public display as part of the file on the matter in the office of the Dockets Management Branch. A determination to grant a stay will be published in the FEDERAL REGISTER if the Commissioner's original decision was so published. Any other determination to grant or to deny a stay may also be published in the FEDERAL REGISTER.

(g) A petition for a stay of action submitted later than 30 days after the date of the decision involved will be denied as untimely unless the Commissioner permits the petition to be filed after 30 days. A petition for a stay of action is considered submitted on the day it is received by the Dockets Management Branch.

(h) The record of the administrative proceeding consists of the following:

(1) The record of the proceeding to which the petition for stay of action is directed.

(2) The petition for stay of action, including all information on which it relies, filed by the Dockets Management Branch.

(3) All comments received on the petition, including all information submitted as a part of the comments.

(4) The Commissioner's decision on the petition under paragraph (e) of this section, including all information identified or filed by the Commissioner with the Dockets Management

Branch as part of the record supporting the decision.

(5) Any FEDERAL REGISTER notices or other documents resulting from the petition.

(6) All documents filed with the Dockets Management Branch under § 10.65(h).

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 54 FR 9034, Mar. 3, 1989]

§ 10.40 Promulgation of regulations for the efficient enforcement of the law.

(a) The Commissioner may propose and promulgate regulations for the efficient enforcement of the laws administered by FDA whenever it is necessary or appropriate to do so. The issuance, amendment, or revocation of a regulation may be initiated in any of the ways specified in § 10.25.

(1) This section applies to any regulation: (i) Not subject to § 10.50 and Part 12, or (ii) if it is subject to § 10.50 and Part 12, to the extent that those provisions make this section applicable.

(2) A regulation proposed by an interested person in a petition submitted under § 10.25(a) will be published in the FEDERAL REGISTER as a proposal if:

(i) The petition contains facts demonstrating reasonable grounds for the proposal; and

(ii) The petition substantially shows that the proposal is in the public interest and will promote the objectives of the act and the agency.

(3) Two or more alternative proposed regulations may be published on the same subject to obtain comment on the different alternatives.

(4) A regulation proposed by an interested person in a petition submitted under § 10.25(a) may be published together with the Commissioner's preliminary views on the proposal and any alternative proposal.

(b) Except as provided in paragraphs (d) and (e) of this section, each regulation must be the subject of a notice of proposed rulemaking published in the FEDERAL REGISTER.

(1) The notice will contain:

(i) The name of the agency;

(ii) the nature of the action, e.g., proposed rule, or notice;

(iii) a summary in the first paragraph describing the substance of the document in easily understandable terms;

(iv) relevant dates, e.g., comment closing date, and proposed effective date(s);

(v) the name, business address, and phone number of an agency contact person who can provide further information to the public about the notice;

(vi) an address for submitting written comments;

(vii) supplementary information about the notice in the form of a preamble that summarizes the proposal and the facts and policy underlying it, includes references to all information on which the Commissioner relies for the proposal (copies or a full list of which are a part of the docket file on the matter in the office of the Dockets Management Branch), and cites the authority under which the regulation is proposed;

(viii) either the terms or substance of the proposed regulation or a description of the subjects and issues involved;

(ix) a reference to the existence or lack of need for an environmental impact statement under § 25.42(b)(3)(ii) or (iii); and

(x) the docket number of the matter, which identifies the docket file established by the Dockets Management Branch for all relevant submissions.

(2) The proposal will provide 60 days for comment, although the Commissioner may shorten or lengthen this time period for good cause. In no event is the time for comment to be less than 10 days.

(3) After publication of the proposed rule, any interested person may request the Commissioner to extend the comment period for an additional specified period by submitting a written request to the Dockets Management Branch stating the grounds for the request. The request is submitted under § 10.35 but should be headed "REQUEST FOR EXTENSION OF COMMENT PERIOD."

(i) A request must discuss the reason comments could not feasibly be submitted within the time permitted, or that important new information will shortly be available, or that sound public policy otherwise supports an extension of the time for comment. The Commissioner may grant or deny the request or may grant an extension for a time period different from that requested. An extension may be limited to specific persons who have made and justified the request, but will ordinarily apply to all interested persons.

(ii) A comment time extension of 30 days or longer will be published in the Federal Register and will be applicable to all interested persons. A comment time extension of less than 30 days will be the subject either of a letter or memorandum filed with the Dockets Management Branch or of a notice published in the Federal Register.

(4) A notice of proposed rulemaking will request that four copies of all comments be submitted to the Dockets Management Branch, except that individuals may submit single copies. Comments will be stamped with the date of receipt and will be numbered chronologically.

(5) Persons submitting comments critical of a proposed regulation are encouraged to include their preferred alternative wording.

(c) After the time for comment on a proposed regulation has expired, the Commissioner will review the entire administrative record on the matter, including all comments and, in a notice published in the Federal Register, will terminate the proceeding, issue a new proposal, or promulgate a final regulation.

(1) The quality and persuasiveness of the comments will be the basis for the Commissioner's decision. The number or length of comments will not ordinarily be a significant factor in the decision unless the number of comments is material where the degree of public interest is a legitimate factor for consideration.

(2) The decision of the Commissioner on the matter will be based solely upon the administrative record.

(3) A final regulation published in the Federal Register will have a preamble stating: (i) The name of the agency, (ii) the nature of the action e.g., final rule, notice, (iii) a summary first paragraph describing the substance of the document in easily understandable terms, (iv) relevant dates, e.g., the rule's effective date and comment closing date, if an opportunity for comment is provided, (v) the name, business address, and phone number of an agency contact person who can provide further information to the public about the notice, (vi) an address for the submission of written comments when they are permitted, (vii) supplementary information about the regulation in the body of the preamble that contains references to prior notices relating to the same matter and a summary of each type of comment submitted on the proposal and the Commissioner's conclusions with respect to each. The preamble is to contain a thorough and comprehensible explanation of the reasons for the Commissioner's decision on each issue.

(4) The effective date of a final regulation may not be less than 30 days after the date of publication in the Federal Register, except for:

(i) A regulation that grants an exemption or relieves a restriction; or

(ii) A regulation for which the Commissioner finds, and states in the notice good cause for an earlier effective date.

(d) The provisions for notice and comment in paragraphs (b) and (c) of this section will apply to interpretive rules and rules of agency practice and procedure except as provided in paragraph (e) of this section. Paragraphs (b) and (c) of this section do not apply to general statements of policy in the form of informational notices published in the Federal Register or to matters involving agency organization.

(e) The requirements of notice and public procedure in paragraph (b) of this section do not apply in the following situations:

(1) When the Commissioner determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In these cases, the notice promulgating the regulation will state the reasons for the determination, and provide an opportunity for comment to determine whether the regulation should subsequently be modified or revoked. A subsequent notice based on those comments may,

but need not, provide additional opportunity for public comment.

(2) Food additive and color additive petitions which are subject to the provisions of § 12.20(b)(2).

(3) New animal drug regulations, which are promulgated under section 512(i) of the act.

(f) In addition to the notice and public procedure required under paragraph (b) of this section, the Commissioner may also subject a proposed or final regulation, before or after publication in the FEDERAL REGISTER, to the following additional procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, or 15.

(3) A notice published in the FEDERAL REGISTER requesting information and views before the Commissioner determines whether to propose a regulation.

(4) A draft of a proposed regulation placed on public display in the office of the Dockets Management Branch. If this procedure is used, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments on the draft proposal may be submitted orally or in writing.

(5) A revised proposal published in the FEDERAL REGISTER, which proposal is subject to all the provisions in this section relating to proposed regulations.

(6) A tentative final regulation or tentative revised final regulation placed on public display in the office of the Dockets Management Branch and, if deemed desirable by the Commissioner, published in the FEDERAL REGISTER. If the tentative regulation is placed on display only, the Commissioner shall publish an appropriate notice in the FEDERAL REGISTER stating that the document is available and specifying the time within which comments may be submitted orally or in writing on the tentative final regulation. The Commissioner shall mail a copy of the tentative final regulation and the FEDERAL REGISTER notice to each person who submitted comments on the proposed regulation if one has been published.

(7) A final regulation published in the FEDERAL REGISTER that provides an opportunity for the submission of further comments, in accordance with paragraph (e)(1) of this section.

(8) Any other public procedure established in this chapter and expressly applicable to the matter.

(g) The record of the administrative proceeding consists of all of the following:

(1) If the regulation was initiated by a petition, the administrative record specified in § 10.30(i).

(2) If a petition for reconsideration or for a stay of action is filed, the administrative record specified in § 10.33(k) and § 10.35(h).

(3) The proposed rule published in the FEDERAL REGISTER, including all information identified or filed by the Commissioner with the Dockets Management Branch on the proposal.

(4) All comments received on the proposal, including all information submitted as a part of the comments.

(5) The notice promulgating the final regulation, including all information identified or filed by the Commissioner with the Dockets Management Branch as part of the administrative record of the final regulation.

(6) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents resulting from the procedures specified in paragraph (f) of this section, but not the transcript of a closed portion of a public advisory committee meeting.

(7) All documents submitted to the Dockets Management Branch under § 10.65(h).

(h) The record of the administrative proceeding closes on the date of publication of the final regulation in the FEDERAL REGISTER unless some other date is specified. Thereafter, any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit it to the Commissioner with a new petition to modify the final regulation.

(i) The Dockets Management Branch shall maintain a chronological list of all regulations proposed and promulgated under this section and § 10.50 (which list will not include regulations resulting from petitions filed and assigned a docket number under § 10.30) showing—

(1) The docket number (for a petition submitted directly to a center, the list also includes the number or other designation assigned by the center, e.g., the number assigned to a food additive petition);

(2) The name of the petitioner, if any;

(3) The subject matter involved; and

(4) The disposition of the petition.

[44 FR 22323, Apr. 13, 1979, as amended at 52 FR 36401, Sept. 29, 1987; 54 FR 9034, Mar. 3, 1989]

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

(a) This section applies to court review of final administrative action taken by the Commissioner, including action taken under §§ 10.25 through 10.40 and § 16.1(b), except action subject to § 10.50 and Part 12.

(b) A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a) or, where applicable, a hearing under § 16.1(b) before any legal action is filed in a court complaining of the action or failure to act. If a court action is filed complaining of the action or failure to act before the submission of the decision on a petition under § 10.25(a) or, where applicable, a hearing under § 16.1(b), the Commissioner shall request dismissal of the court action or referral to the agency for an initial administrative determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201.

(c) A request that administrative action be stayed must first be the subject of an administrative decision based upon a petition for stay of action submitted under § 10.35 before a request is made that a court stay the action. If a court action is filed requesting a stay of administrative action before the Commissioner's decision on a petition submitted in a timely manner pursuant to § 10.35, the Commissioner shall request dismissal of the court action or referral to the agency for an initial determination on the grounds of a failure to exhaust administrative remedies, the lack of final agency action as required by 5 U.S.C. 701 et seq., and the lack of an actual controversy as required by 28 U.S.C. 2201. If a court action is filed requesting a stay of administrative action after a petition for a stay of action is denied because it was submitted after expiration of the time period provided under § 10.35, or after the time for submitting such a petition has expired, the Commissioner will request dismissal of the court action on the ground of a failure to exhaust administrative remedies.

(d) The Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a guideline issued under § 10.90, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b), or on the issuance of a final regulation published in accordance with § 10.40.

(1) It is the position of FDA except as otherwise provided in paragraph (d)(2) of this section, that:

(i) Final agency action exhausts all administrative remedies and is ripe for preenforcement judicial review as of the date of the final decision, unless applicable law explicitly requires that the petitioner take further action before judicial review is available;

(ii) An interested person is affected by, and thus has standing to obtain judicial review of final agency action; and

(iii) It is not appropriate to move to dismiss a suit for preenforcement judicial review of final agency action on the ground that indispenable parties are not joined or that it is an unconsented suit against the United States if the defect could be cured by amending the complaint.

(2) The Commissioner shall object to judicial review of a matter if:

(i) The matter is committed by law to the discretion of the Commissioner, e.g., a decision to recommend or not to recommend civil or criminal enforcement action under sections 302, 303, and 304 of the act; or

(ii) Review is not sought in a proper court.

(e) An interested person may request judicial review of a final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action, except that in accordance with paragraph (c) of this section, the person shall request a stay by the Commissioner under § 10.35 before requesting a stay by the court.

(f) The Commissioner shall take the position in an action for judicial review under 5 U.S.C. 701 et seq., whether or not it includes a request for a declaratory judgment under 28 U.S.C. 2201, or in any other case in which the validity of administrative action is properly challenged, that the validity of the action must be determined solely on the basis of the administrative record specified in §§ 10.30(i), 10.33(k), 10.35(h), 10.40(g), and 16.80(a) or the administrative record applicable to any decision or action under the regulations referenced in § 16.1(b), and that additional information or views may not be considered. An interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a).

(g) The Commissioner requests that all petitions for judicial review of a particular matter be filed in a single U.S. District court. If petitions are filed in more than one jurisdiction, the Commissioner will take appropriate action to prevent a multiplicity of suits in various jurisdictions, such as:

(1) A request for transfer of one or more suits to consolidate separate actions, under 28 U.S.C. 1404(a) or 28 U.S.C. 2112(a);

(2) A request that actions in all but one jurisdiction be stayed pending the conclusion of one proceeding;

(3) A request that all but one action be dismissed pending the conclusion of one proceeding, with the suggestion that the other plaintiffs intervene in that one suit; or

(4) A request that one of the suits be maintained as a class action in behalf of all affected persons.

(h)(1) For the purpose of 28 U.S.C. 2112(a), a copy of any petition filed in any U.S. Court of Appeals challenging a final action of the Commissioner shall be sent by certified mail, return receipt requested, or by personal delivery to the Chief Counsel of FDA. The petition copy shall be time-stamped by the clerk of the court when the original is filed with the court. The petition copy should be addressed to: Office of the Chief Counsel (GCF-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. The Chief Counsel requests that the purpose of all petitions mailed or delivered to the Office of Chief Counsel to satisfy 28 U.S.C. 2112(a) be clearly identified in a cover letter.

(2) If the Chief Counsel receives two or more petitions filed in two or more U.S. Courts of Appeals for review of any agency action within 10 days of the effective date of that action for the purpose of judicial review, the Chief Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period, in accordance with the applicable rule of the panel.

(3) For the purpose of determining whether a petition for review has been received within the 10-day period under paragraph (h)(2) of this section, the petition shall be considered to be received on the date of delivery, if personally delivered. If the delivery is accomplished by mail, the date of receipt shall be the date noted on the return receipt card.

(i) Upon judicial review of administrative action under this section:

(1) If a court determines that the administrative record is inadequate to support the action, the Commissioner shall determine whether to proceed with such action.

(i) If the Commissioner decides to proceed with the action, the court will be requested to remand the matter to the agency to reopen the administrative proceeding and record, or on the Commissioner's own initiative the administrative proceeding and record may be reopened upon receipt of the court determination. A reopened administrative proceeding will be conducted under the provisions of this part and in accordance with any directions of the court.

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further administrative proceedings, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further administrative proceedings.

(2) If a court determines that the administrative record is adequate, but the rationale for the action must be further explained:

(i) The Commissioner shall request either that further explanation be provided in writing directly to the court without further administrative proceedings, or that the administrative proceeding be reopened in accordance with paragraph (i)(1)(i) of this section; and

(ii) If the Commissioner concludes that the public interest requires that the action remain in effect pending further court or administrative proceedings, the court will be requested not to stay the matter in the interim and the Commissioner shall expedite the further proceedings.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 6886, Feb. 15, 1989; 54 FR 9034, Mar. 3, 1989]

§ 10.50 Promulgation of regulations and orders after an opportunity for a formal evidentiary public hearing.

(a) The Commissioner shall promulgate regulations and orders after an opportunity for a formal evidentiary public hearing under Part 12 whenever all of the following apply:

(1) The subject matter of the regulation or order is subject by statute to an opportunity for a formal evidentiary public hearing.

(2) The person requesting the hearing has a right to an opportunity for a hearing and submits adequate justification for the hearing as required by §§ 12.20 through 12.22 and other applicable provisions in this chapter, e.g., §§ 314.200, 314.300, 514.200, and 601.7(a).

(b) The Commissioner may order a formal evidentiary public hearing on any matter whenever it would be in the public interest to do so.

(c) The provisions of the act, and other laws, that afford a person who would be adversely affected by administrative action an opportunity for a formal evidentiary public hearing as listed below. The list imparts no right to a hearing where the statutory section provides no opportunity for a hearing.

(1) Section 401 on definitions and standards for food.

(2) Section 403(j) on regulations for labeling of foods for special dietary uses.

(3) Section 404(a) on regulations for emergency permit control.

(4) Section 406 on tolerances for poisonous substances in food.

(5) Section 409 (c), (d), and (h) on food additive regulations.

(6) Section 501(b) on tests or methods of assay for drugs described in official compendia.

(7) Section 502(d) on regulations designating habit forming drugs.

(8) Section 502(h) on regulations designating requirements for drugs liable to deterioration.

(9) Section 502(n) on prescription drug advertising regulations.

(10) Section 506(c) on insulin regulations.

(11) Section 507(f) on regulations for antibiotic drug certification.

(12) Section 512(n)(5) on regulations for animal antibiotic drugs and certification requirements.

(13) Section 706 (b) and (c) on regulations for color additive listing and certification.

(14) Section 4(a) of the Fair Packaging and Labeling Act on food, drug, device, and cosmetic labeling.

(15) Section 5(c) of the Fair Packaging and Labeling Act on additional economic regulations for food, drugs, devices, and cosmetics.

(16) Section 505 (d) and (e) on new drug applications.

(17) Section 512 (d), (e) and (m) (3) and (4) on new animal drug applications.

(18) Section 515(g) on device premarket approval applications and product development protocols.

(19) Section 351(a) of the Public Health Service Act on plant and product licenses for a biologic.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9034, Mar. 3, 1989]

§ 10.55 Separation of functions; ex parte communications.

(a) This section applies to any matter subject by statute to an opportunity for a formal evidentiary public hearing, as listed in § 10.50(c), and any matter subject to a hearing before a Public Board of Inquiry under Part 13.

(b) In the case of a matter listed in § 10.50(c) (1) through (10) and (12) through (15):

(1) An interested person may meet or correspond with any FDA representative concerning a matter prior to publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry on the matter; the provisions of § 10.65 apply to the meetings and correspondence; and

(2) Upon publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry, the following separation of functions apply:

(i) The center responsible for the matter is, as a party to the hearing, responsible for all investigative functions and for presentation of the position of the center at the hearing and in any pleading or oral argument before the Commissioner. Representatives of the center may not participate or advise in any decision except as witness or counsel in public proceedings. There is to be no other communication between representatives of the center and representatives of the office of the Commissioner concerning the matter before the decision of the Commissioner. The Commissioner may, however, designate representatives of a center to advise the office of the Commissioner, or designate members of that office to advise a center. The designation will be in writing and filed with the Dockets Management Branch no later than the time specified in paragraph (b)(2) of this section for the application of separation of functions. All members of FDA other than representatives of the involved center (except those specifically designated otherwise) shall be available to advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(ii) The Chief Counsel for FDA shall designate members of the office of General Counsel to advise and participate with the center in its functions in the hearing and members who are to advise the office of the Commissioner in its functions related to the hearing and the final decision. The members of the office of General Counsel designated to advise the center may not participate or advise in any decision of the Commissioner except as counsel in public proceedings. The designation is to be in the form of a memorandum filed with the Dockets Management Branch and made a part of the administrative record in the proceeding. There may be no other communication between those members of the office of General Counsel designated to advise the office of the Commissioner and any other persons in the office of General Counsel or in the involved center with respect to the matter prior to the decision of the Commissioner. The Chief Counsel may assign new attorneys to advise either the center or the office of the Commissioner at any stage of the proceedings. The Chief Counsel will ordinarily advise and participate with the office of the Commissioner in its functions relating to the hearing and the final decision.

(iii) The office of the Commissioner is responsible for the agency review and final decision of the matter, with the advice and participation of anyone in FDA other than representatives of the involved center and those members of the office of General Counsel designated to assist in the center's functions in the hearing.

(c) In a matter listed in § 10.50(c) (11) and (16) through (19), the provisions relating to separation of functions set forth in §§ 314.200(f), 314.300, 514.200, and 601.7(a) are applicable before publication of a notice announcing a formal evidentiary public hearing or a hearing before a Public Board of Inquiry. Following publication of the notice of hearing, the rules in paragraph (b)(2) of this section apply.

(d) Except as provided in paragraph (e) of this section, between the date that separation of functions applies under paragraph (b) or (c) of this section and the date of the Commissioner's decision on the matter, communication concerning the matter involved in the hearing will be restricted as follows:

(1) No person outside the agency may have an ex parte communication with the presiding officer or any person representing the office of the Commissioner concerning the matter in the hearing. Neither the presiding officer nor any person representing the office of the Commissioner may have any ex parte communication with a person outside the agency concerning the matter in the hearing. All communications are to be public communications, as witness or counsel, under the applicable provisions of this part.

(2) A participant in the hearing may submit a written communication to the office of the Commissioner with respect to a proposal for settlement. These communications are to be in the form of pleadings, served on all other participants, and filed with the Dockets Management Branch like any other pleading.

(3) A written communication contrary to this section must be immediately served on all other participants and filed with the Dockets Management Branch by the presiding officer at the hearing, or by the Commissioner, depending on who received the communication. An oral communication contrary to this section must be immediately recorded in a written memorandum and similarly served on all other participants and filed with the Dockets Management Branch. A person, including a representative of a participant in the hearing, who is involved in an oral communication contrary to this section, must, if possible, be made available for cross-examination during the hearing with respect to the substance of that conversation. Rebuttal testimony pertinent to a written or oral communication contrary to this section will be permitted. Cross-examination and rebuttal testimony will be transcribed and filed with the Dockets Management Branch.

(e) The prohibitions specified in paragraph (d) of this section apply to a person who knows of a notice of hearing in advance of its publication from the time the knowledge is acquired.

(f) The making of a communication contrary to this section may, consistent with the interests of justice and the policy of the underlying statute, result in a decision adverse to the person knowingly making or causing the making of such a communication.

[44 FR 22323, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989]

§ 10.60 Referral by court.

(a) This section applies when a Federal, State, or local court holds in abeyance, or refers to the Commissioner, any matter for an initial administrative determination under § 10.25(c) or § 10.45(b).

(b) The Commissioner shall promptly agree or decline to accept a court referral. Whenever feasible in light of agency priorities and resources, the Commissioner shall agree to accept a referral and shall proceed to determine the matter referred.

(c) In reviewing the matter, the Commissioner may use the following procedures:

(1) Conferences, meetings, discussions, and correspondence under § 10.65.

(2) A hearing under Parts 12, 13, 14, 15, or 16.

(3) A notice published in the FEDERAL REGISTER requesting information and views.

(4) Any other public procedure established in other sections of this chapter and expressly applicable to the matter under those provisions.

(d) If the Commissioner's review of the matter results in a proposed rule, the provisions of § 10.40 or § 10.50 also apply.

§ 10.65 Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner. Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(b) The Commissioner may conclude that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before FDA, at which any interested person may participate.

(1) The Commissioner shall give public notice through the public calendar described in § 10.100(a) of the time and place of the meeting and of the matters to be discussed, and may also publish notice of the meeting.

(2) The meeting will be informal, i.e., any interested person may attend and participate in the discussion without prior notice to the agency unless the notice of the meeting specifies otherwise.

(3) No official transcript or recording of the meeting will be made unless it appears to the agency that it will be useful. A written memorandum summarizing the substance of the meeting will be prepared by an FDA representative in all cases.

(c) A meeting with a person outside the Department, including a person in the executive or legislative branch of the Federal Government, concerning a pending court case, administrative hearing, or other regulatory action or decision, which involves more than a brief description of the matter, is to be summarized in a written memorandum, which is filed in the administrative file on the matter.

(d) Every person outside the Federal Government may request and obtain a private meeting with a representative of FDA in agency offices to discuss a matter.

(1) The person requesting a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom there is a commercial arrangement within the meaning of § 20.81(a). Neither FDA nor any other person may require the attendance of a person who is not an employee of the executive branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and FDA.

(2) FDA will determine which representatives of the Agency will attend the meeting. The person requesting the meeting may request but not require or preclude the attendance of a specific FDA employee.

(3) Whenever appropriate (e.g., the meeting involves a matter covered by paragraph (c) of this section or other important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be desirable), a written memorandum summarizing the substance of the meeting will be prepared by an FDA representative.

(4) A person who wishes to attend a private meeting, but who either is not permitted to attend by the person requesting the meeting or by FDA or who cannot attend because the meeting is conducted by telephone, may obtain a separate meeting with FDA to discuss the same matter or an additional matter.

(e) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the Agency. In pursuing this responsibility the following general policy applies where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the Agency.

(1) A person outside the executive branch may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate, but may do so where it is in the public interest and will promote the objectives of the act.

(2) The agency representative may request that the meeting be open if that would be in the public interest. The agency representative may decline to participate in a meeting held

as a private meeting if that will best serve the public interest.

(3) An agency representative may not knowingly participate in a meeting which is closed on the basis of sex, race, or religion.

(4) A meeting, whether open or closed, is subject to paragraph (d)(3) of this section with respect to memoranda summarizing the substance of the meeting.

(f) Representatives of FDA may initiate a meeting or correspondence with any person outside the Federal Government on any matter concerning the laws administered by the Commissioner.

(1) A meeting initiated by FDA representatives which involves a small number of interested persons, for example, a meeting with a petitioner or with two manufacturers of a particular product which requires additional testing or with a trade association employee to discuss an industry labeling problem, may be a private meeting. A meeting initiated by FDA representatives which involves a large number of interested persons, for example, 10 manufacturers of an ingredient in a discussion of appropriate testing or labeling, must be held as an open conference or meeting under paragraph (b) of this section.

(2) Whenever appropriate (e.g., the meeting involves a matter covered by paragraph (c) of this section or another important matter, a decision on an issue, or statements or advice or conclusions to which future reference may be desirable), a written memorandum summarizing the substance of the meeting will be prepared by an FDA representative.

(g) A person who participates in a meeting described in paragraphs (b) through (f) of this section may also prepare and submit to FDA for inclusion in the administrative file a written memorandum summarizing the substance of the meeting.

(h) Memoranda of meetings prepared by an FDA representative or by any other person and all correspondence which relate to a matter pending before the agency will promptly be filed in the administrative file of the proceeding.

(i) A meeting with a representative of Congress relating to a pending or potential investigation, inquiry, or hearing by a congressional committee or a Member of Congress will be summarized in a written memorandum which is to be forwarded to the Food and Drug Administration, Office of Legislative Affairs. This provision does not restrict the right of an agency employee to participate in the meeting.

(j) A meeting of an advisory committee is subject to the requirements of part 14.

(k) Under 42 U.S.C. 263l(a)(8), a log or summary is to be made of all meetings between representatives of FDA and industry and other interested parties to implement the Radiation Control for Health and Safety Act of 1968.

§ 10.70 Documentation of significant decisions in administrative file.

(a) This section applies to every significant FDA decision on any matter under the laws administered by the Commissioner, whether it is raised formally, for example, by a petition or informally, for example, by correspondence.

(b) FDA employees responsible for handling a matter are responsible for insuring the completeness of the administrative file relating to it. The file must contain:

(1) Appropriate documentation of the basis for the decision, including relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documents; and

(2) The recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter.

(i) The recommendations and decisions are to reveal significant controversies or differences of opinion and their resolution.

(ii) An agency employee working on a matter and, consistent with the prompt completion of other assignments, an agency employee who has worked on a matter may record individual views on that matter in a written memorandum, which is to be placed in the file.

(c) A written document placed in an administrative file must:

(1) Relate to the factual, scientific, legal or related issues under consideration;

(2) Be dated and signed by the author;

(3) Be directed to the file, to appropriate supervisory personnel, and to other appropriate employees, and show all persons to whom copies were sent;

(4) Avoid defamatory language, intemperate remarks, undocumented charges, or irrelevant matters (e.g., personnel complaints);

(5) If it records the views, analyses, recommendations, or decisions of an agency employee in addition to the author, be given to the other employees; and

(6) Once completed (i.e., typed in final form, dated, and signed) not be altered or removed. Later additions to or revisions of the document must be made in a new document.

(d) Memoranda or other documents that are prepared by agency employees and are not in the administrative file have no status or effect.

(e) FDA employees working on a matter have access to the administrative file on that matter, as appropriate for the conduct of their work. FDA employees who have worked on a matter have access to the administrative file on that matter so long as attention to their assignments is not impeded. Reasonable restrictions may be placed upon access to assure proper cataloging and storage of documents, the availability of the file to others, and the completeness of the file for review.

§ 10.75 Internal agency review of decisions.

(a) A decision of an FDA employee, other than the Commissioner, on a matter, is subject to review by the employee's supervisor under the following circumstances:

(1) At the request of the employee.

(2) On the initiative of the supervisor.

(3) At the request of an interested person outside the agency.

(4) As required by delegations of authority.

(b) The review will be made by consultation between the employee and the supervisor or by review of the administrative file on the matter, or both. The review will ordinarily follow the established agency channels of supervision or review for that matter.

(c) An interested person outside the agency may request internal agency review of a decision through the established agency channels of supervision or review. Personal review of these matters by center directors or the office of the Commissioner will occur for any of the following purposes:

(1) To resolve an issue that cannot be resolved at lower levels within the agency (e.g., between two parts of a center or other component of the agency, between two centers or other components of the agency, or between the agency and an interested person outside the agency).

(2) To review policy matters requiring the attention of center or agency management.

(3) In unusual situations requiring an immediate review in the public interest.

(4) As required by delegations of authority.

(d) Internal agency review of a decision must be based on the information in the administrative file. If an interested person presents new information not in the file, the matter will be returned to the appropriate lower level in the agency for reevaluation based on the new information.

[44 FR 22323, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985]

§ 10.80 Dissemination of draft Federal Register notices and regulations.

(a) A representative of FDA may discuss orally or in writing with an interested person ideas and recommendations for notices or regulations. FDA welcomes assistance in developing ideas for, and in gathering the information to support, notices and regulations.

(b) Notices and proposed regulations. (1) Once it is determined that a notice or proposed regulation will be prepared, the general concepts may be discussed by a representative of FDA with an interested person. Details of a draft of a notice or proposed regulation may be discussed with a person outside the executive branch only with the specific permission of the Commissioner. The permission must be in writing and filed with the Dockets Management Branch.

(2) A draft of a notice or proposed regulation or its preamble, or a portion of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER. A draft of a notice or proposed regulation made available in this manner may, without the prior permission of the Commissioner, be discussed with an interested person to clarify and resolve questions raised and concerns expressed about the draft.

(c) After publication of a notice or proposed regulation in the FEDERAL REGISTER, and before preparation of a draft of the final notice or regulation, a representative of FDA may discuss the proposal with an interested person as provided in paragraph (b)(2) of this section.

(d) Final notices and regulations. (1) Details of a draft of a final notice or regulation may be discussed with an interested person outside the executive branch only with the specific permission of the Commissioner. The permission must be in writing and filed with the Dockets Management Branch.

(2) A draft of a final notice or regulation or its preamble, or any portion of either, may be furnished to an interested person outside the executive branch only if it is made available to all interested persons by a notice published in the FEDERAL REGISTER, except as otherwise provided in paragraphs (g) and (j) of this section. A draft of a final notice or regulation made available to an interested person in this manner may, without the prior permission of the Commissioner, be discussed as provided in paragraph (b)(2) of this section.

(i) The final notice or regulation and its preamble will be prepared solely on the basis of the administrative record.

(ii) If additional technical information from a person outside the executive branch is necessary to draft the final notice or regulation or its preamble, it will be requested by FDA in general terms and furnished directly to the Dockets Management Branch to be included as part of the administrative record.

(iii) If direct discussion by FDA of a draft of a final notice or regulation or its preamble is required with a person outside the executive branch, appropriate protective procedures will be undertaken to make certain that a full and impartial administrative record is established. Such procedures may include either:

(*a*) The scheduling of an open public meeting under § 10.65(b) at which interested persons may participate in review of and comment on the draft document; or

(*b*) The preparation of a tentative final regulation or tentative revised final regulation under § 10.40(f)(6), on which interested persons will be given an additional period of time for oral and written comment.

(e) After a final regulation is published, an FDA representative may discuss any aspect of it with an interested person.

(f) In addition to the requirements of this section, the provisions of § 10.55 apply to the promulgation of a regulation subject to § 10.50 and Part 12.

(g) A draft of a final food additive color additive, or new animal drug regulation or a proposed or final antibiotic regulation may be furnished to the petitioner for comment on the technical accuracy of the regulation. Every meeting with a petitioner relating to the draft will be recorded in a written memorandum, and all memoranda and correspondence will be filed with the Dockets Management Branch as part of the administrative record of the regulation under the provisions of § 10.65.

(h) In accordance with 42 U.S.C 263f, the Commissioner shall consult with interested persons and with the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) before prescribing any performance standard for an electronic product. Accordingly, the Commissioner shall publish in the FEDERAL REGISTER an announcement when a

best copy available

proposed or final performance standard, including any amendment, is being considered for an electronic product, and any draft of any proposed or final standard will be furnished to an interested person upon request and may be discussed in detail.

(i) The provisions of § 10.65 apply to meetings and correspondence relating to draft notices and regulations.

(j) The provisions of this section restricting discussion and disclosure of draft notices and regulations do not apply to situations covered by §§ 20.83 through 20.89.

[44 FR Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 10.85 Advisory opinions.

(a) An interested person may request an advisory opinion from the Commissioner on a matter of general applicability.

(1) The request will be granted whenever feasible.

(2) The request may be denied if:

(i) The request contains incomplete information on which to base an informed advisory opinion;

(ii) The Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved;

(iii) The matter is adequately covered by a prior advisory opinion or a regulation;

(iv) The request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability; or

(v) The Commissioner otherwise concludes that an advisory opinion would not be in the public interest.

(b) A request for an advisory opinion is to be submitted in accordance with § 10.20, is subject to the provisions of § 10.30 (c) through (l), and must be in the following form:

(Date) ——————————

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

REQUEST FOR ADVISORY OPINION

The undersigned submits this request for an advisory opinion of the Commissioner of Food and Drugs with respect to —— (the general nature of the matter involved).

A. *Issues involved.*

(A concise statement of the issues and questions on which an opinion is requested.)

B. *Statement of facts and law.*

(A full statement of all facts and legal points relevant to the request.)

The undersigned certifies that, to the best of his/her knowledge and belief, this request includes all data, information, and views relevant to the matter, whether favorable or unfavorable to the position of the undersigned, which is the subject of the request.

(Signature) ——————————
(Person making request) ——————————
(Mailing address) ——————————
(Telephone number) ——————————

(c) The Commissioner may respond to an oral or written request to the agency as a request for an advisory opinion, in which case the request will be filed with the Dockets Management Branch and be subject to this section.

(d) A statement of policy or interpretation made in the following documents, unless subsequently repudiated by the agency or overruled by a court, will constitute an advisory opinion:

(1) Any portion of a FEDERAL REGISTER notice other than the text of a proposed or final regulation, e.g., a notice to manufacturers or a preamble to a proposed or final regulation.

(2) Trade Correspondence (T.C. Nos. 1-431 and 1A-8A) issued by FDA between 1938 and 1946.

(3) Compliance policy guides issued by FDA beginning in 1968 and codified in the Compliance Policy Guides manual.

(4) Other documents specifically identified as advisory opinions, e.g., advisory opinions on the performance standard for diagnostic X-ray systems, issued before July 1, 1975, and filed in a permanent public file for prior advisory opinions maintained by the Freedom of Information Staff (HFI-35).

(5) Guidelines issued by FDA under § 10.90(b).

(e) An advisory opinion represents the formal position of FDA on a matter and except as provided in paragraph (f) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with an advisory opinion which has not been amended or revoked.

(f) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to an advisory opinion before amending or revoking the opinion. This action may be taken only with the approval of the Commissioner, who may not delegate this function. Appropriate amendment or revocation of the advisory opinion involved will be expedited.

(g) An advisory opinion may be amended or revoked at any time after it has been issued. Notice of amendment or revocation will be given in the same manner as notice of the advisory opinion was originally given or in the FEDERAL REGISTER, and will be placed on public display as part of the file on the matter in the office of the Dockets Management Branch. The Dockets Management Branch shall maintain a separate chronological index of all advisory opinions filed. The index will specify the date of the request for the advisory opinion, the date of the opinion, and identification of the appropriate file.

(h) Action undertaken or completed in conformity with an advisory opinion which has subsequently been amended or revoked is acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. Whenever possible, an amended or revoked advisory opinion will state when action previously undertaken or completed does not remain acceptable, and any transition period that may be applicable.

(i) An interested person may submit written comments on an advisory opinion or modified advisory opinion. Four copies of any comments are to be sent to the Dockets Management Branch for inclusion in the public file on the advisory opinion. Individuals may submit only one copy. Comments will be considered in determining whether further modification of an advisory opinion is warranted.

(j) An advisory opinion may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(k) A statement made or advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981]

§ 10.90 Food and Drug Administration regulations, guidelines, recommendations, and agreements.

(a) *Regulations.* FDA regulations are promulgated in the FEDERAL REGISTER under § 10.40 or § 10.50 and codified in the Code of Federal Regulations. Regulations may contain provisions that will be enforced as legal requirements, or which are intended only as guidelines and recommendations, or both. The dissemination of draft notices and regulations is subject to § 10.80.

(b) *Guidelines.* FDA guidelines are included in the public file of guidelines established by the Dockets Management Branch, under this paragraph, unless they have been published as regulations under paragraph (a) of this section.

(1) Guidelines establish principles or practices of general applicability and do not include decisions or advice on particular situations. Guidelines relate to performance characteristics, preclinical and clinical test procedures, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. Guidelines state procedures or standards of general applicability that are not legal requirements but are acceptable to FDA for a subject matter which falls within the laws administered by the Commissioner.

(i) A person may rely upon a guideline with assurance that it is acceptable to FDA, or may follow different procedures or standards. When different procedures or standards are chosen, a person may, but is not required to, discuss the matter in advance with FDA to prevent the expenditure of money and effort on activity that may later be determined to be unacceptable.

(ii) Use of testing guidelines established by FDA assures acceptance of a test as scientifically valid, if properly conducted, but does not assure approval of any ingredient or product so tested. Test results or other available information may require disapproval or additional testing.

(2) A guideline represents the formal position of FDA on a matter and, except as provided in paragraph (b)(3) of this section, obligates the agency to follow it until it is amended or revoked. The Commissioner may not recommend legal action against a person or product with respect to an action taken in conformity with a guideline issued under this section that has not been amended or revoked.

(3) In unusual situations involving an immediate and significant danger to health, the Commissioner may take appropriate civil enforcement action contrary to a guideline before amending or revoking the guideline as provided in paragraph (b)(5) of this section. This action may be taken only with the approval of the Commissioner, who may not delegate that function. Amendment or revocation of the guideline involved will be expedited.

(4) A guideline will be included in the public file upon approval of the guideline by the Commissioner or relevant center director and publication of a notice of its availability. The notice will state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline.

(5) A guideline may be amended or revoked by the Commissioner or relevant center director and publication of a notice of the amendment or revocation. The notice will state (i) the title of the guideline, (ii) the subject matter it covers, and (iii) the office or individual responsible for maintaining the guideline. All original guidelines and subsequent amendments will be retained in the public file permanently so that a complete record of the development of each guideline is available.

(6) Action undertaken or completed in conformity with a guideline which has subsequently been amended or revoked will remain acceptable to FDA unless the Commissioner determines that substantial public interest considerations preclude continued acceptance. This determination may be made at the time of or after amendment or revocation of the guideline. Whenever possible, notice of an amended or revoked guideline will state when it has been determined that action previously undertaken or completed in conformity with a prior guideline does not remain acceptable, and any transition period that may be applicable.

(7) The notice of a guideline or of an amended or revoked guideline will state that an interested person may submit written comments on the guideline. Four copies of comments are to be sent to the Dockets Management Branch for inclusion in the public file on the guideline. The comments will be considered in determining whether further amendments to or reinstitution of a guideline are warranted.

(8) A guideline may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement.

(9) A statement relating to acceptable procedures or standards given by an FDA employee orally, or in writing but not under § 10.85 of this section, is an informal communication that represents the best judgment of that employee at that time but does not constitute a guideline, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate the agency to the views expressed.

(10) Because of the large number of analytical methods involved in FDA activities, their length and complexity and the volume and frequency of amendment, paragraph (b)(4) of this section does not apply to analytical methods except to the extent that the Commissioner concludes that particu-

lar analytical methods should be included in the public file for a particular purpose. FDA analytical methods are available for public disclosure under Part 20.

(11) The dissemination of draft guidelines is subject to the same provisions as the dissemination of draft notices and regulations under § 10.80.

(c) *Recommendations.* In addition to the guidelines subject to paragraph (b) of this section, FDA often formulates and disseminates recommendations about matters which are authorized by, but do not involve direct regulatory action under, the laws administered by the Commissioner, e.g., model State and local ordinances, or personnel practices for reducing radiation exposure, issued under 42 U.S.C 243 and 263d(b). These recommendations may, in the discretion of the Commissioner, be handled under the procedures established in paragraph (b) of this section, except that the recommendations will be included in a separate public file of recommendations established by the Dockets Management Branch and will be separated from the guidelines in the notice of availability published in the FEDERAL REGISTER, or be published in the FEDERAL REGISTER as regulations under paragraph (a) of this section.

(d) *Agreements.* Formal agreements, memoranda of understanding, or other similar written documents executed by FDA and another person will be included in the public file on agreements established by the Freedom of Information Staff (HFI-35) under § 20.108. A document not included in the public file is deemed to be rescinded and has no force or effect whatever.

[44 FR 22323, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 10.95 Participation in outside standard-setting activities.

(a) *General.* This section applies to participation by FDA employees in standard-setting activities outside the agency. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA encourages employee participation in outside standard-setting activities that are in the public interest.

(b) *Standard-setting activities by other Federal Government agencies.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Freedom of Information Staff.

(3) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitations will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(c) *Standard-setting activities by State and local government agencies and by United Nations organizations and other international organizations and foreign governments pursuant to treaty.* (1) An FDA employee may participate in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide.

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI-35).

(3) The availability for public disclosure of records relating to the activity will be governed by Part 20.

(4) If a member of the public is invited by FDA to present views to, or to accompany, the FDA employee at a meeting, the invitation will be extended to a representative sampling of the public, including consumer groups, industry associations, professional societies, and academic institutions.

(5) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(d) *Standard-setting activities by private groups and organizations.* (1) an FDA employee may engage in these activities after approval of the activity under procedures specified in the current agency Staff Manual Guide. A request for official participation must be made by the group or organization in writing, must describe the scope of the activity, and must demonstrate that the minimum standards set out in paragraph (d)(5) of this section are met. Except as provided in paragraph (d)(7) of this section, a request that is granted will be the subject of a letter from the Commissioner or the center director to the organization stating—

(i) Whether participation by the individual will be as a voting or nonvoting liaison representative;

(ii) That participation by the individual does not connote FDA agreement with, or endorsement of, any decisions reached; and

(iii) That participation by the individual precludes service as the deciding official on the standard involved if it should later come before FDA. The deciding official is the person who signs a document ruling upon the standard.

(2) The letter requesting official FDA participation, the approval form, and the Commissioner's or center director's letter, together with all pertinent background information describing the activities involved, will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI-35).

(3) The availability for public disclosure of records relating to the activities will be governed by Part 20.

(4) An FDA employee appointed as the liaison representative to an activity shall refer all requests for information about or participation in the activity to the group or organization responsible for the activity.

(5) The following minimum standards apply to an outside private standard-setting activity in which FDA employees participate:

(i) The activity will be based upon consideration of sound scientific and technological information, will permit revision on the basis of new information, and will be designed to protect the public against unsafe, ineffective, or deceptive products or practices.

(ii) The activity and resulting standards will not be designed for the economic benefit of any company, group, or organization, will not be used for such antitrust violations as fixing prices or hindering competition, and will not involve establishment of certification or specific approval of individual products or services.

(iii) The group or organization responsible for the standard-setting activity must have a procedure by which an interested person will have an opportunity to provide information and views on the activity and standards involved, without the payment of fees, and the information and views will be considered. How this is accomplished, including whether the presentation will be in person or in writing, will be decided by the group or organization responsible for the activity.

(6) Membership of an FDA employee in an organization that also conducts a standard-setting activity does not invoke the provisions of this section unless the employee participates in the standard-setting activity. Participation in a standard-setting activity is subject to this section.

(7) The Commissioner may determine in writing that, because direct involvement by FDA in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, the participation is exempt from the requirements of paragraph (d)(1)(ii) and/or (iii) of this section. This determination will be included in the public file on standard-setting activities established by the Freedom of Information Staff and in any relevant administrative file. The activity may include the establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and

preventive medicine practices by national and international organizations.

(8) Because of the close daily cooperation between FDA and the associations of State and local government officials listed below in this paragraph, and the large number of agency employees who are members of or work with these associations, participation in the activities of these associations is exempt from paragraphs (d)(1) through (7) of this section, except that a list of the committees and other groups of these associations will be included in the public file on standard-setting activities established by the Freedom of Information Staff (HFI-35):

(i) American Association of Food Hygiene Veterinarians (AAFHV).

(ii) American Public Health Association (APHA).

(iii) Association of American Feed Control Officials, Inc. (AAFCO).

(iv) Association of Food and Drug Officials (AFDO).

(v) Association of Official Analytical Chemists (AOAC).

(vi) Association of State and Territorial Health Officials (ASTHO).

(vii) Conference for Food Protection (CFP).

(viii) Conference of State Health and Environmental Managers (COSHEM).

(ix) Conference of Radiation Control Program Directors (CRCPD).

(x) International Association of Milk, Food, and Environmental Sanitation, Inc. (IAMFES).

(xi) Interstate Shellfish Sanitation Conference (ISSC).

(xii) National Association of Boards of Pharmacy (NABP).

(xiii) National Association of Departments of Agriculture (NADA).

(xiv) National Conference on Interstate Milk Shipments (NCIMS).

(xv) National Conference of Local Environmental Health Administrators (NCLEHA).

(xvi) National Conference on Weights and Measures (NCWW).

(xvii) National Environmental Health Association (NEHA).

(xviii) National Society of Professional Sanitarians (NSPS).

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[44 FR 22323, Apr. 13, 1979, as amended at 46 FR 8455, Jan. 27, 1981; 52 FR 35064, Sept. 17, 1987; 54 FR 9035, Mar. 3, 1989]

§ 10.100 Public calendars.

(a) *Prospective public calendar of public proceedings.* (1) A public calendar will be prepared and made publicly available each week showing, to the extent feasible, for the following 4 weeks, the public meetings, conferences, hearings, advisory committee meetings, seminars, and other public proceedings of FDA, and other significant public events involving FDA, e.g., congressional hearings.

(2) A copy of this public calendar will be placed on public display in the following places: (i) Dockets Management Branch.

(ii) Office of the Associate Commissioner for Public Affairs.

(iii) A central place in each center.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

(b) *Retrospective public calendar of meetings.* (1) A public calendar will be prepared and made publicly available each week showing for the previous week meetings with persons outside the executive branch and other significant events involving the representatives of FDA designated under paragraph (b)(3) of this section, but telephone conversations will be included on an optional basis and meetings with the working press, except for "house organs" (i.e., publications of firms that manufacture or distribute regulated products, or industry associations), and with on-site contractors will not be included. Meetings with members of the judiciary representatives of Congress, or staffs of congressional committees will be included when the meeting relates to a pending court case, administrative hearing, or other regulatory action or decision and involves more than a brief description of the matter.

(2) The calendar will include all meetings, conferences, seminars, social events sponsored by the regulated industry, and speeches. The calendar will specify the date and the person and subject matter involved. When more than one FDA representative is

in attendance, only the presiding or head representative will report the meeting on the public calendar. If a large number of persons is involved, the name of each need not be specified. Meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in FDA) will not be reported.

(3) The following FDA representatives and their deputies are subject to the requirements of paragraphs (b) (1) and (2) of this section:

(i) Commissioner of Food and Drugs.

(ii) Deputy Commissioner.

(iii) Associate Commissioners.

(iv) Executive and Special Assistants to the Commissioner.

(v) [Reserved]

(vi) Director, National Center for Toxicological Research.

(vii) Center Directors.

(viii) Chief Counsel for the Food and Drug Administration, or any representative of that office attending on behalf of the Chief Counsel.

(4) A copy of the public calendar will be placed on public display in the following places:

(i) Dockets Management Branch.

(ii) Office of the Associate Commissioner for Public Affairs.

(iii) A central place in each center.

(iv) A central place in each field office.

(v) A central place at the National Center for Toxicological Research.

[44 FR 22323, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989]

§ 10.105 Representation by an organization.

(a) An organization may represent its members by filing petitions, comments, and objections, and otherwise participating in an administrative proceeding subject to this part.

(b) A petition, comment, objection, or other representation by an organization will not abridge the right of a member to take individual action of a similar type, in the member's own name.

(c) It is requested that each organization participating in FDA administrative proceedings file annually with the Dockets Management Branch a current list of all of the members of the organization.

(d) The filing by an organization of an objection or request for hearing under §§ 12.20 through 12.22 does not provide a member a legal right with respect to the objection or request for hearing that the member may individually exercise. A member of an organization wishing to file an objection or request for hearing must do so individually.

(e) In a court proceeding in which an organization participates, the Commissioner will take appropriate legal measures to have the case brought or considered as a class action or otherwise as binding upon all members of the organization except those specifically excluded by name. Regardless of whether the case is brought or considered as a class action or as otherwise binding upon all members of the organization except those specifically excluded by name, the Commissioner will take the position in any subsequent suit involving the same issues and a member of the organization that the issues are precluded from further litigation by the member under the doctrines of collateral estoppel or res judicata.

§ 10.110 Settlement proposals.

At any time in the course of a proceeding subject to this part, a person may propose settlement of the issues involved. A participant in a proceeding will have an opportunity to consider a proposed settlement. Unaccepted proposals of settlement and related matters, e.g., proposed stipulations not agreed to, will not be admissible in evidence in an FDA administrative proceeding. FDA will oppose the admission in evidence of settlement information in a court proceeding or in another administrative proceeding.

Subpart C—Electronic Media Coverage of Public Administrative Proceedings; Guideline on Policy and Procedures

SOURCE: 49 FR 14726, Apr. 13, 1984, unless otherwise noted.

§ 10.200 Scope.

This guideline describes FDA's policy and procedures applicable to electronic media coverage of agency public administrative proceedings. It is a guideline intended to clarify and explain FDA's policy on the presence and operation of electronic recording equipment at such proceedings and to assure uniform and consistent application of practices and procedures throughout the agency.

§ 10.203 Definitions.

(a) "Public administrative proceeding" as used in this guideline means any FDA proceeding which the public has a right to attend. This includes a formal evidentiary public hearing as set forth in Part 12, a public hearing before a Public Board of Inquiry as set forth in Part 13, a public hearing before a Public Advisory Committee as set forth in Part 14, a public hearing before the Commissioner as set forth in Part 15, a regulatory hearing before FDA as set forth in Part 16, consumer exchange meetings, and Commissioner's public meetings with health professionals.

(b) "Advance notice" as used in this guideline means written or telephone notification to FDA's Office of Public Affairs (Press Relations Staff) of intent to electronically record an agency public administrative proceeding.

(c) "Electronic recording" as used in this guideline means any visual or audio recording made by videotape recording equipment or moving film camera, and/or other electronic recording equipment.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

§ 10.204 General.

(a) FDA has for many years willingly committed itself to a policy of openness. In many instances FDA has sought to make the open portions of agency public administrative proceedings more accessible to public participation. Similarly, FDA has sought, wherever possible, to allow full written media access to its proceedings, so that members of the press would have the opportunity to provide first-hand reports. However, because electronic media coverage presents certain difficulties that are easier to resolve with advance notice to the agency and all participants, FDA believes that codification of its policy will facilitate and further increase media access to its public administrative proceedings. The agency intends to refer to this guideline when notices of hearing, or individual advisory committee meetings, are published in the FEDERAL REGISTER. Thus, all parties to a proceeding will be on notice that the proceeding may be recorded electronically and any person interested in videotaping or otherwise recording the proceeding will be notified that there are established procedures to be followed.

(b) The designated presiding officer of a public administrative proceeding retains the existing discretionary authority set forth in specific regulations pertaining to each type of administrative proceeding to regulate the conduct of the proceeding over which he or she presides. The responsibilities of the presiding officer, established elsewhere in Parts 10 through 16, include an obligation to be concerned with the timely conduct of a hearing, the limited availability of certain witnesses, and reducing disruptions to the proceeding which may occur. Each proceeding varies, and the presiding officer cannot anticipate all that might occur. Discretionary authority to regulate conduct at a proceeding has traditionally been granted to presiding officers to enable them to fulfill their responsibility to maintain a fair and orderly hearing conducted in an expeditious manner.

(c) This guideline provides the presiding officer with a degree of flexibility in that it sets forth the agency's policy as well as the procedures that presiding officers should ordinarily follow, but from which they may depart in particular situations if necessary, subject to the presumption of openness of public proceedings to electronic media coverage. The presiding officer's discretion to establish additional procedures or to limit electronic coverage is to be exercised only in the unusual circumstances defined in this guideline. Even though a presiding officer may establish additional procedures or limits as may be required in a particular situation, he or she will be guided by the policy expressed in this guideline in establishing these conditions. The presiding officer may also be less restrictive, taking into account such factors as the duration of a hearing and the design of the room.

(d) If a portion or all of a proceeding is closed to the public because material is to be discussed that is not disclosable to the public under applicable laws, the proceeding also will be closed to electronic media coverage.

(e) The agency requests advance notice of intent to record a proceeding electronically to facilitate the orderly conduct of the proceeding. Knowledge of anticipated media coverage will allow the presiding officer to make any special arrangements required by the circumstances of the proceeding. The agency believes that this guideline establishes sufficiently specific criteria to promote uniformity.

(f) The agency would like to allow all interested media representatives to videotape a proceeding in which they have an interest. However, should space limitations preclude a multitude of cameras, the presiding officer may require pool sharing. In such a case, pool sharing arrangements of the resulting videotape should be made between those allowed to film and those who were excluded. Arrangements for who is designated to present the pool and a method of distributing the resulting film or tape may be determined by the established networks' pooling system. However, the agency has a strong commitment to ensuring that media representatives other than the major networks also be able to obtain a copy of the tape at cost. FDA is concerned that if the network pool representative wishes to record only a short portion of a proceeding, but an excluded party wishes to record the entire proceeding, confusion will result. The agency expects the interested media representatives to negotiate a suitable agreement among themselves before commencement of the proceeding. For example, the network pool representatives might agree to record a portion of the proceeding up to a break in the proceeding, at which time, while the network representative is disassembling equipment, another media representative might set up to continue recording. If an agreement cannot be reached before the proceeding, the agency will use the time of receipt of any advance notice to determine the representation for each category of media, e.g., one network reporter, one independent reporter. The agency recommends that parties intending to videotape provide as much advance notice as possible, so that the agency may best respond to the needs of the electronic media.

(g) To ensure the timely conduct of agency hearings and to prevent disruptions, equipment is to be stationary during a proceeding and should be set up and taken down when the proceeding is not in progress. As noted previously, the presiding officer may, at his or her discretion, be less restrictive if appropriate.

(h) The agency recognizes that electronic media representatives may desire only short footage of a proceeding, a facsimile of the proceeding, and/or interview opportunities and may be unnecessarily restricted by requirements for setting up before a proceeding and then waiting until a break in the proceeding before being permitted to take down their equipment. To accommodate this possibility, FDA's Press Relations Staff will attempt to make arrangements to respond to such needs by, for example, requesting that the presiding officer provide a break shortly after commencement of the proceeding to permit take down of equipment.

(i) The agency is making a full commitment to allowing, whenever possible, electronic coverage of its public administrative proceedings subject to the limited restrictions established in this guideline.

§ 10.205 Electronic media coverage of public administrative proceedings.

(a) A person may record electronically any open public administrative proceeding, subject to the procedures specified in this guideline. The procedures include a presumption that agency public proceedings are open to the electronic media. Whenever possible, FDA will permit all interested persons access to record agency public administrative proceedings. Restrictions other than those listed in § 10.206 will be imposed only under exceptional circumstances.

(b) A videotape recording of an FDA public administrative proceeding is not an official record of the proceeding. The only official record is the written transcript of the proceeding, which is taken by the official reporter.

§ 10.206 Procedures for electronic media coverage of agency public administrative proceedings.

(a) To facilitate the agency's response to media needs, a person intending to videotape an FDA public administrative proceeding should, whenever possible, provide advance notice to the Press Relations Staff (HFI-20), Office of Public Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, in writing or by telephone (telephone 301-443-4177), at least 48 hours in advance of the proceeding. The Press Relations Staff will inform the presiding officer that the proceeding will be attended by representatives of the electronic media, and ascertain whether any special provisions in addition to those set forth in this subpart are required by the presiding officer. If so, the Press Relations Staff will function as a liaison between the presiding officer and the person intending to record the proceeding in facilitating any procedures in addition to those outlined in this subpart. The presiding officer will not deny access for failure to provide a 48-hour advance notice. Any advance notice may describe the intended length of recording if known, the amount and type of equipment to be used, and any special needs such as interviews.

(b) Cameras should be completely set up before a proceeding is scheduled to begin or during a break in the proceeding and should remain standing in the area designated for electronic media equipment. Cameras may be taken down only during breaks or after the hearing is over. Roving cameras will not be permitted during the proceeding. Any artificial lighting should be unobtrusive. Microphones, like cameras, should be in place before the start of a proceeding and may be taken down as indicated in this paragraph.

(c) When space in the hearing room is limited, the presiding officer may restrict the number of cameras or the equipment present. Should such a restriction become necessary, the pool arrangements are the responsibility of the participating media. The agency encourages the network pool to make copies of the tape, film, or other product available at cost to nonpool participants. However, if this is not possible, the agency may need to use the time of receipt of any advance notice to determine the representation for each category, e.g., one network reporter, one independent reporter, etc.

(d) "Off the record" portions of a proceeding may not be videotaped.

(e) Before or during the proceeding, the presiding officer may establish other conditions specific to the proceeding for which the request is being made. These conditions may be more or less restrictive than those stated in this guideline, except that the presiding officer shall observe the agency's presumption of openness of its public proceedings to the electronic media. Only a substantial and clear threat to the agency's interests in order, fairness, and timeliness authorizes the presiding officer to impose additional restrictions. This threat must outweigh the public interest in electronic media coverage of agency proceedings. Additional restrictions shall be narrowly drawn to the particular circumstances. The following factors are listed to assist presiding officers in determining whether the agency's interest is sufficiently compelling to call for the unusual step of imposing additional restrictions. Generally this step is justified when one of the following factors is met:

(1) Electronic recording would result in a substantial likelihood of disruption that clearly cannot be contained by the procedures established in paragraphs (a) through (d) of this section.

(2) Electronic recording would result in a substantial likelihood of prejudicial impact on the fairness of the proceeding or the substantive discussion in a proceeding.

(3) There is a substantial likelihood that a witness' ability to testify may be impaired due to unique personal circumstances such as the age or psychological state of the witness or the particularly personal or private nature of the witness' testimony, if the witness' testimony were electronically recorded.

(f) Before the proceeding, the Press Relations Staff will, upon request, provide written copies of any additional conditions imposed by the presiding officer (as described in paragraph (e) of this section) to requesting members of the media. Any appeals should be made in accordance with paragraph (h) of this section.

(g) The presiding officer retains authority to restrict or discontinue videotaping or other recording of a proceeding, or parts of a proceeding, should such a decision become necessary. The presiding officer's responsibility to conduct the hearing includes the right and duty to remove a source of substantial disruption. In exercising his or her authority, the presiding officer shall observe the presumption that agency public proceedings are open to the electronic media. The presiding officer shall exercise his or her discretion to restrict or discontinue electronic coverage of a public proceeding, or portions of a public proceeding, only if he or she determines that the agency's interest in the fair and orderly administrative process is substantially threatened. A clear and substantial threat to the integrity of agency proceedings must clearly outweigh the public interest in electronic media coverage of the proceedings before additional restrictions are imposed on the electronic media during the course of the proceedings. The factors noted in paragraph (e) of this section indicate the kind of substantial threat to the agency interests that may require imposing additional restrictions during the course of the proceedings. If additional requirements are established during the hearing, the presiding officer shall notify immediately the Deputy Commissioner of Food and Drugs of that fact by telephone and submit a written explanation of the circumstances that necessitated such an action within 24 hours or sooner if requested by the Deputy Commissioner. In the absence or unavailability of the Deputy Commissioner, the presiding officer shall notify the Associate Commissioner for Regulatory Affairs.

(h) A decision by a presiding officer, made either before the proceeding or during the course of a proceeding, to establish requirements in addition to the minimum standards set forth in this guideline may be appealed by any adversely affected person who intends to record the proceeding electronically. Appeals may be made in writing or by phone to the Deputy Commissioner or, in his or her absence, to the Associate Commissioner for Regulatory Affairs. The filing of an appeal, whether before or during a proceeding, does not require the presiding officer to interrupt the proceeding. However, the Deputy Commissioner or, in his or her absence, the Associate Commissioner for Regulatory Affairs will resolve an appeal as expeditiously as possible so as to preserve, to the extent possible, the reporters' opportunity to record the proceedings.

[49 FR 14726, Apr. 13, 1984, as amended at 54 FR 9035, Mar. 3, 1989]

PART 12—FORMAL EVIDENTIARY PUBLIC HEARING

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AUTHORITY: Sec. 201 *et seq.*, Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 *et seq.*); sec.1 *et seq.*, Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 *et seq.*); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec 301 *et seq.*, Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 *et seq.*); sec 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 *et seq.*, Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 *et seq.*); secs. 1-9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1-10, Ch. 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 *et seq.*, Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 *et seq.*); sec. 1 *et seq.*, Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 *et seq.*).

SOURCE: 44 FR 22339, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 12.1 Scope.

The procedures in this part apply when—

(a) A person has a right to an opportunity for a hearing under the laws specified in § 10.50; or

(b) The Commissioner concludes that it is in the public interest to hold a formal evidentiary public hearing on any matter before FDA.

Subpart B—Initiation of Proceedings

§ 12.20 Initiation of a hearing involving the issuance, amendment, or revocation of a regulation.

(a) A proceeding under section 409(f), 502(n), 507(f), 512(n)(5), 701(e), or 706(d) of the act or section 4 or 5 of the Fair Packaging and Labeling Act may be initiated—

(1) By the Commissioner on the Commissioner's own initiative, e.g., as provided in § 170.15 for food additives; or

(2) By a petition—

(i) In the form specified elsewhere in this chapter, e.g., the form for a color additive petition in § 71.1 or for an antibiotic petition in § 431.50; or

(ii) If no form is specified, by a petition under § 10.30.

(b) If the Commissioner receives a petition under paragraph (a)(2) of this section, the Commissioner will—

(1) If it involves any matter subject to section 701(e) of the act or section 4 or 5 of the Fair Packaging and Label-

ing Act, and meets the requirements for filing, follow the provisions of § 10.40 (b) through (f);

(2) If it involves a color additive or food additive, and meets the requirements for filing in §§ 71.1 and 71.2, or in §§171.1, 171.6, 171.7, and 171.100, publish a notice of filing of the petition within 30 days after the petition is filed instead of a notice of proposed rulemaking.

(c) The Commissioner may issue, amend, or revoke an antibiotic regulation without the requirements of notice and public procedure in § 10.40(b) or delayed effective date in § 10.40(c)(4), on the Commissioner's own initiative or as a result of a petition containing the required evidence of safety and effectiveness in the circumstances described in § 10.40(e)(1).

(d) The notice promulgating the regulation will describe how to submit objections and requests for hearing.

(e) On or before the 30th day after the date of publication of a final regulation, or of a notice withdrawing a proposal initiated by a petition under § 10.25(a), a person may submit to the Commissioner written objections and a request for a hearing. The 30-day period may not be extended except that additional information supporting an objection may be received after 30 days upon a showing of inadvertent omission and hardship, and if review of the objection and request for hearing will not thereby be impeded. If, after a final color additive regulation is published, a petition or proposal relating to the regulation is referred to an advisory committee in accordance with section 706(b)(5)(C) of the act, objections and requests for a hearing may be submitted on or before the 30th day after the date on which the order confirming or modifying the Commissioner's previous order is published.

§ 12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.

(a) A proceeding under section 505 (d) or (e), 512 (d), (e), (m) (3) or (4), of section 515(g)(1) of the act, or section 351(a) of the Public Health Service Act, may be initiated—

(1) By the Commissioner on the Commissioner's own initiative;

(2) By a petition in the form specified elsewhere in this chapter, e.g., § 314.50 for new drug applications, § 514.1 for new animal drug applications, § 514.2 for applications for animal feeds, or § 601.3 for licenses for biologic products; or

(3) By a petition under § 10.30.

(b) A notice of opportunity for hearing on a proposal to deny or revoke approval of all or part of an order will be published together with an explanation of the grounds for the proposed action. The notice will describe how to submit requests for hearing. A person subject to the notice has 30 days after its issuance to request a hearing. The 30-day period may not be extended.

(c) The Commissioner may use an optional procedure specified in § 10.30(h) to consider issuing, amending, or revoking an order.

(d) In a proceeding under sections 505(e), 512(e) or (m), or 515(e) of the act in which a party wishes to apply for reimbursement of certain expenses under the Equal Access to Justice Act (5 U.S.C. 504 and 504 note), FDA will follow the Department of Health and Human Services' regulations in 45 CFR Part 13.

(5 U.S.C. 504 and 504 note; secs. 505, 512, 515, 701(a), 52 Stat. 1052-1053 as amended, 1055, 82 Stat. 343-351 as amended, 90 Stat. 552-559 as amended (21 U.S.C. 355, 360b, 360c, 371(a)))

[44 FR 22339, Apr. 13, 1979, as amended at 47 FR 25734, June 15, 1982; 54 FR 9035, Mar. 3, 1989]

§ 12.22 Filing objections and requests for a hearing on a regulation or order.

(a) Objections and requests for a hearing under § 12.20(d) must be submitted to the Dockets Management Branch and will be accepted for filing if they meet the following conditions:

(1) They are submitted within the time specified in § 12.20(e).

(2) Each objection is separately numbered.

(3) Each objection specifies with particularity the provision of the regulation or proposed order objected to.

(4) Each objection on which a hearing is requested specifically so states. Failure to request a hearing on an ob-

jection constitutes a waiver of the right to a hearing on that objection.

(5) Each objection for which a hearing is requested includes a detailed description and analysis of the factual information to be presented in support of the objection. Failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under § 12.24, and do not limit the evidence that may be presented if a hearing is granted.

(i) A copy of any report, article, survey, or other written document relied upon must be submitted, except if the document is—

(*a*) An FDA document that is routinely publicly available;

(*b*) A recognized medical or scientific textbook that is readily available to the agency; or

(*c*) A designated journal listed in § 510.95.

(ii) A summary of the nondocumentary testimony to be presented by any witnesses relied upon must be submitted.

(b) Requests for hearing submitted under § 12.21 will be submitted to the Dockets Management Branch and will be accepted for filing if they meet the following conditions:

(1) They are submitted on or before the 30th day after the date of publication of the notice of opportunity for hearing.

(2) They comply with §§ 314.200, 514.200, or 601.7(a).

(c) If an objection or request for a public hearing fails to meet the requirements of this section and the deficiency becomes known to the Dockets Management Branch, the Dockets Management Branch shall return it with a copy of the applicable regulations, indicating those provisions not complied with. A deficient objection or request for a hearing may be supplemented and subsequently filed if submitted within the 30-day time period specified in § 12.20(e) or § 12.21(b).

(d) If another person objects to a regulation issued in response to a petition submitted under § 12.20(a)(2), the petitioner may submit a written reply to the Dockets Management Branch.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 12.23 Notice of filing of objections.

As soon as practicable after the expiration of the time for filing objections to and requests for hearing on agency action involving the issuance, amendment, or revocation of a regulation under sections 502(n), 701(e), or 706(d) of the act or sections 4 or 5 of the Fair Packaging and Labeling Act, the Commissioner shall publish a notice in the FEDERAL REGISTER specifying those parts of the regulation that have been stayed by the filing of proper objections and, if no objections have been filed, stating that fact. The notice does not constitute a determination that a hearing is justified on any objections or requests for hearing that have been filed. When to do so will cause no undue delay, the notice required by this section may be combined with the notices described in §§ 12.28 and 12.35.

§ 12.24 Ruling on objections and requests for hearing.

(a) As soon as possible the Commissioner will review all objections and requests for hearing filed under § 12.22 and determine—

(1) Whether the regulation should be modified or revoked under § 12.26;

(2) Whether a hearing has been justified; and

(3) Whether, if requested, a hearing before a Public Board of Inquiry under Part 13 or before a public advisory committee under Part 14 or before the Commissioner under Part 15 has been justified.

(b) A request for a hearing will be granted if the material submitted shows the following:

(1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law.

(2) The factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions.

(3) The data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate.

(4) Resolution of the factual issue in the way sought by the person is adequate to justify the action requested. A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal. A hearing will be granted upon proper objection and request when a food standard or other regulation is shown to have the effect of excluding or otherwise affecting a product or ingredient.

(5) The action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

(6) The requirements in other applicable regulations, e.g., §§ 10.20, 12.21, 12.22, 314.200, 314.300, 514.200, and 601.7(a), and in the notice promulgating the final regulation or the notice of opportunity for hearing are met.

(c) In making the determination in paragraph (a) of this section, the Commissioner may use any of the optional procedures specified in § 10.30(h) or in other applicable regulations, e.g., §§ 314.200, 314.300, 514.200, and 601.7(a).

(d) If it is uncertain whether a hearing has been justified under the principles in paragraph (b) of this section, and the Commissioner concludes that summary decision against the person requesting a hearing should be considered, the Commissioner may serve upon the person by registered mail a proposed order denying a hearing. The person has 30 days after receipt of the proposed order to demonstrate that the submission justifies a hearing.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 12.26 Modification or revocation of regulation or order.

If the Commissioner determines upon review of an objection or request for hearing that the regulation or order should be modified or revoked, the Commissioner will promptly take such action by notice in the Federal Register. Further objections to or requests for hearing on the modification or revocation may be submitted under §§ 12.20 through 12.22 but no further issue may be taken with other provisions in the regulation or order. Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in due course.

§ 12.28 Denial of hearing in whole or in part.

If the Commissioner determines upon review of the objections or requests for hearing that a hearing is not justified, in whole or in part, a notice of the determination will be published.

(a) The notice will state whether the hearing is denied in whole or in part. If the hearing is denied in part, the notice will be combined with the notice of hearing required by § 12.35, and will specify the objections and requests for hearing that have been granted and denied.

(1) Any denial will be explained. A denial based on an analysis of the information submitted to justify a hearing will explain the inadequacy of the information.

(2) The notice will confirm or modify or stay the effective date of the regulation or order involved.

(b) The record of the administrative proceeding relating to denial of a public hearing in whole or in part on an objection or request for hearing consists of the following:

(1) If the proceeding involves a regulation—

(i) The documents specified in § 10.40(g);

(ii) The objections and requests for hearing filed by the Dockets Management Branch;

(iii) If the proceeding involves a color additive regulation referred to an advisory committee in accordance with section 706(b)(5)(C) of the act, the committee's report and the record of the committee's proceeding; and

(iv) The notice denying a formal evidentiary public hearing.

(2) If the proceeding involves an order—

(i) The notice of opportunity for hearing;

(ii) The requests for hearing filed by the Dockets Management Branch;

(iii) The transcripts, minutes of meetings, reports, FEDERAL REGISTER notices, and other documents constituting the record of any of the optional procedures specified in § 12.24(c) used by the Commissioner, but not the transcript of a closed portion of a public advisory committee meeting; and

(iv) The notice denying the hearing.

(c) The record specified in paragraph (b) of this section is the exclusive record for the Commissioner's decision on the complete or partial denial of a hearing. The record of the proceeding will be closed as of the date of the Commissioner's decision unless another date is specified. A person who requested and was denied a hearing may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35. A person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a petition under § 10.25(a) to modify the final regulation or order.

(d) Denial of a request for a hearing in whole or in part is final agency action reviewable in the courts, under the statutory provisions governing the matter involved, as of the date of publication of the denial in the FEDERAL REGISTER.

(1) Before requesting a court for a stay of action pending review, a person shall first submit a petition for a stay of action under § 10.35.

(2) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions on a particular matter.

(3) The time for filing a petition for judicial review of a denial of a hearing on an objection or issue begins on the date the denial is published in the FEDERAL REGISTER, (i) When an objection or issues relates to a regulation, if a hearing is denied on all objections and issues concerning a part of the proposal the effectiveness of which has not been deferred pending a hearing on other parts of the proposal; or (ii) when an issue relates to an order, if a hearing is denied on all issues relating to a particular new drug application, new animal drug application, device premarket approval application or product development protocol, or biologics license. The failure to file a petition for judicial review within the period established in the statutory provision governing the matter involved constitutes a waiver of the right to judicial review of the objection or issue, regardless whether a hearing has been granted on other objections and issues.

§ 12.30 Judicial review after waiver of hearing on a regulation.

(a) A person with a right to submit objections and a request for hearing under § 12.20(d) may submit objections and waive the right to a hearing. The waiver may be either an explicit statement, or a failure to request a hearing, as provided in 12.22(a)(4).

(b) If a person waives the right to a hearing, the Commissioner will rule upon the person's objections under §§ 12.24 through 12.28. As a matter of discretion, the Commissioner may also order a hearing on the matter under any of the provisions of this part.

(c) If the Commissioner rules adversely on a person's objection, the person may petition for judicial review in a U.S. Court of Appeals under the act.

(1) The record for judicial review is the record designated in § 12.28(b)(1).

(2) The time for filing a petition for judicial review begins as of the date of publication of the Commissioner's ruling on the objections.

§ 12.32 Request for alternative form of hearing.

(a) A person with a right to request a hearing may waive that right and request one of the following alternatives:

(1) A hearing before a Public Board of Inquiry under Part 13.

(2) A hearing before a public advisory committee under Part 14.

(3) A hearing before the Commissioner under Part 15.

(b) The request—

(1) May be on the person's own initiative or at the suggestion of the Commissioner.

(2) Must be submitted in the form of a citizen petition under § 10.30 before publication of a notice of hearing under § 12.35 or a denial of hearing under § 12.28; and

(3) Must be—

(i) In lieu of a request for a hearing under this part; or

(ii) If submitted after or with a request for hearing, in the form of a waiver of the right to request a hearing conditioned on an alternative form of hearing. Upon acceptance by the Commissioner, the waiver becomes binding and may be withdrawn only by waiving any right to any form of hearing unless the Commissioner determines otherwise.

(c) When more than one person requests and justifies a hearing under this part, an alternative form of hearing may by used only if all the persons concur and waive their right to request a hearing under this part.

(d) The Commissioner will determine whether an alternative form of hearing should be used, and if so, which alternative is acceptable, after considering the requests submitted and the appropriateness of the alternatives for the issues raised in the objections. The Commissioner's acceptance is binding unless, for good cause, the Commissioner determines otherwise.

(e) The Commissioner will publish a notice of an alternative form of hearing setting forth the following information:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.

(3) The time, date, and place of the hearing, or a statment that such information will be contained in a later notice.

(4) The parties to the hearing.

(5) The issues at the hearing. The statement of issues determines the scope of the hearing.

(6) If the hearing will be conducted by a Public Board of Inquiry, the time within which—

(i) The parties should submit nominees for the Board under § 13.10(b);

(ii) A notice of participation under § 12.45 should be filed; and

(iii) Participants should submit written information under § 13.25. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing before the Board. The portions listed will be placed on public display in the office of the Dockets Management Branch before the notice is published. Additional copies of material already submitted under § 13.25 need not be included with any later submissions.

(f)(1) The decision of a hearing before a Public Board of Inquiry or a public advisory committee under this section has legal status of and will be handled as an initial decision under § 12.120.

(2) The decision of a public hearing before the Commissioner under this section will be issued as a final order. The final order will have the same content as an initial decision, as specified in § 12.120 (b) and (c).

(3) Thereafter, the participants in the proceeding may pursue the administrative and court remedies specified in §§ 12.120 through 12.159.

(g) If a hearing before a public advisory committee or a hearing before the Commissioner is used as an alternative form of hearing, all submissions will be made to the Dockets Management Branch, and § 10.20(j) governs their availability for public examination and copying.

(h) This section does not affect the right to an opportunity for a hearing before a public advisory committee under section 515(g)(2) of the act regarding device premarket approval applications and product development protocols. Advisory committee hearing procedures are found in Part 14.

§ 12.35 Notice of hearing; stay of action.

(a) If the Commissioner determines upon review of the objections and requests for hearing that a hearing is justified on any issue, the Commissioner will publish a notice setting forth the following:

(1) The regulation or order that is the subject of the hearing.

(2) A statement specifying any part of the regulation or order that has been stayed by operation of law or in the Commissioner's discretion.

(3) The parties to the hearing.

(4) The issues of fact on which a hearing has been justified.

(5) A statement of any objections or requests for hearing for which a hearing has not been justified, which are subject to § 12.28.

(6) The presiding officer, or a statement that the presiding officer will be designated in a later notice.

(7) The time within which notices of participation should be filed under § 12.45.

(8) The date, time, and place of the prehearing conference, or a statement that the date, time, and place will be announced in a later notice. The prehearing conference may not commence until after the time expires for filing the notice of participation required by § 12.45(a).

(9) The time within which participants should submit written information and views under § 12.85. The notice will list the contents of the portions of the administrative record relevant to the issues at the hearing. The portions listed will be placed on public display in the office of the Dockets Management Branch before the notice is published. Additional copies of material already submitted under § 12.85 need not be included with any later submissions.

(b) The statement of the issues determines the scope of the hearing and the matters on which evidence may be introduced. The issues may be revised by the presiding officer. A participant may obtain interlocutory review by the Commissioner of a decision by the presiding officer to revise the issues to include an issue on which the Commissioner has not granted a hearing or to eliminate an issue on which a hearing has been granted.

(c) A hearing is deemed to begin on the date of publication of the notice of hearing.

(Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 321 et seq.); sec 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679 (b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.); the Agriculture, Rural Development, and Related Agencies Bill (Pub. L. 95-448, 92 Stat. 1073, 1091); and 21 CFR 5.1)

[44 FR 22339, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 12.37 Effective date of a regulation.

(a) If no objections are filed and no hearing is requested on a regulation under § 12.20(e), the regulation is effective on the date specified in the regulation as promulgated.

(b) The Commissioner shall publish a confirmation of the effective date of the regulation. The FEDERAL REGISTER document confirming the effective date of the regulation may extend the time for compliance with the regulation.

§ 12.38 Effective date of an order.

(a) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) does not request a hearing, the Commissioner will—

(1) Publish a final order denying or withdrawing approval of an NDA, NADA, device premarket approval application, or biologics license, in whole or in part, or revoking a device product development protocol or notice of completion, or declaring that such a protocol has not been completed, and stating the effective date of the order; and

(2) If the order involves withdrawal of approval of an NADA, forthwith revoke, in whole or in part, the applicable regulation, under section 512(i) of the act.

(b) If a person who is subject to a notice of opportunity for hearing under § 12.21(b) requests a hearing and others do not, the Commissioner may issue a final order covering all the drug or device products at once or may issue more than one final order covering different drug or device products at different times.

Subpart C—Appearance and Participation

§ 12.40 Appearance.

(a) A person who has filed a notice of participation under § 12.45 may appear in person or by counsel or other representative in any hearing and, subject to § 12.89, may be heard concerning all relevant issues.

(b) The presiding officer may strike a person's appearance for violation of the rules of conduct in § 12.90.

§ 12.45 Notice of participation.

(a) Within 30 days after publication of the notice of hearing under § 12.35, a person desiring to participate in a hearing is to file with the Dockets Management Branch under § 10.20 a notice of participation in the following form:

(Date)

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

NOTICE OF PARTICIPATION

Docket No. ——

Under 21 CFR Part 12, please enter the participation of:

(Name) ————————
(Street address) ————————
(City and State) ————————
(Telephone number) ————————

Service on the above will be accepted by:

(Name) ————————
(Street address) ————————
(City and State) ————————
(Telephone number) ————————

The following statements are made as part of this notice of participation:

A. *Specific interests.* (A statement of the specific interest of the person in the proceeding, including the specific issues of fact concerning which the person desires to be heard. This part need not be completed by a party to the proceeding.)

B. *Commitment to participate.* (A statement that the person will present documentary evidence or testimony at the hearing and will comply with the requirements of 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, with the requirements of 21 CFR 13.25.)

(Signed) ————————

(b) An amendment to a notice of participation should be filed with the Dockets Management Branch and served on all participants.

(c) No person may participate in a hearing who has not filed a written notice of participation or whose participation has been stricken under paragraph (e) of this section.

(d) The presiding officer may permit the late filing of a notice of participation upon a showing of good cause.

(e) The presiding officer may strike the participation of a person for nonparticipation in the hearing or failure to comply with any requirement of this subpart, e.g., disclosure of information as required by § 12.85 or the prehearing order issued under § 12.92. Any person whose participation is stricken may petition the Commissioner for interlocutory review.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[44 FR 22339, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981]

§ 12.50 Advice on public participation in hearings.

(a) *Designated agency contact.* All inquiries from the public about scheduling, location, and general procedures should be addressed to the Associate Commissioner for Regulatory Affairs (HFC-220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or telephone 301-443-3480. The staff of the Associate Commissioner for Regulatory Affairs will attempt to respond promptly to all inquiries from members of the public, as well as to simple requests for information from participants in hearings.

(b) *Hearing schedule changes.* Requests by hearing participants for changes in the schedule of a hearing or for filing documents, briefs, or other pleadings should be made in writing directly to the Administrative Law Judge (HF-3), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) *Legal advice to individuals.* FDA does not have the resources to provide legal advice to members of the public concerning participation in hearings. Furthermore, to do so would compromise the independence of the Commissioner's office and invite charges of improper interference in the hearing process. Accordingly, the Associate Commissioner for Regulatory Affairs will not answer questions about the strengths or weaknesses of a party's position at a hearing, litigation strategy, or similar matters.

(d) *Role of the office of the Chief Counsel.* Under no circumstances will the office of the Chief Counsel of FDA directly provide advice about a hearing to any person who is participating or may participate in the hearing. In every hearing, certain attorneys in the office are designated to represent the center or centers whose action is the subject of the hearing. Other members of the office, including ordinarily the Chief Counsel, are designated to advise the Commissioner on a final decision in the matter. It is not compatible with these functions, nor would it be professionally responsible, for the attorneys in the office of the Chief Counsel also to advise other participants in a hearing, or for any attorney who may be called on to advise the Commissioner to respond to inquiries from other participants in the hearing, for such participants may be urging views contrary to those of the center involved or to what may ultimately be the final conclusions of the Commissioner. Accordingly, members of the office of the Chief Counsel, other than the attorneys responsible for representing the center whose action is the subject of the hearing, will not answer questions about the hearing from any participant or potential participant.

(e) *Communication between participants and attorneys.* Participants in a hearing may communicate with the attorneys responsible for representing the center whose action is the subject of the hearing, in the same way that they may communicate with counsel for any other party in interest about the presentation of matters at the hearing. It would be inappropriate to bar discussion of such matters as stipulations of fact, joint presentation of witnesses, or possible settlement of hearing issues. Members of the public, including participants at hearings, are advised, however, that all such communications, including those by telephone, will be recorded in memoranda that can be filed with the Dockets Management Branch.

[44 FR 22329, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989]

Subpart D—Presiding Officer

§ 12.60 Presiding officer.

The presiding officer in a hearing will be the Commissioner, a member of the Commissioner's office to whom the responsibility for the matter involved has been delegated, or an administrative law judge qualified under 5 U.S.C. 3105.

§ 12.62 Commencement of functions.

The functions of the presiding officer begin upon designation and end upon the filing of the initial decision.

§ 12.70 Authority of presiding officer.

The presiding officer has all powers necessary to conduct a fair, expeditious, and orderly hearing, including the power to—

(a) Specify and change the date, time, and place of oral hearings and conferences;

(b) Establish the procedures for use in developing evidentiary facts, including the procedures in § 12.92(b) and to rule on the need for oral testimony and cross-examination under § 12.87(b);

(c) Prepare statements of the areas of factual disagreement among the participants;

(d) Hold conferences to settle, simplify, or determine the issues in a hearing or to consider other matters that may expedite the hearing;

(e) Administer oaths and affirmations;

(f) Control the course of the hearing and the conduct of the participants;

(g) Examine witnesses and strike their testimony if they fail to respond fully to proper questions;

(h) Rule on, admit, exclude, or limit evidence;

(i) Set the time for filing pleadings;

(j) Rule on motions and other procedural matters;

(k) Rule on motions for summary decision under § 12.93;

(l) Conduct the hearing in stages if the number of parties is large or the issues are numerous and complex;

(m) Waive, suspend, or modify any rule in this subpart under § 10.19 if the presiding officer determines that no party will be prejudiced, the ends of justice will be served, and the action is in accordance with law;

(n) Strike the participation of any person under § 12.45(e) or exclude any person from the hearing under § 12.90, or take other reasonable disciplinary action; and

(o) Take any action for the fair, expeditious, and orderly conduct of the hearing.

§ 12.75 Disqualification of presiding officer.

(a) A participant may request the presiding officer to disqualify himself/herself and withdraw from the proceeding. The ruling on any such request may be appealed in accordance with § 12.97(b).

(b) A presiding officer who is aware of grounds for disqualification shall withdraw from the proceeding.

§ 12.78 Unavailability of presiding officer.

(a) If the presiding officer is unable to act for any reason, the Commissioner will assign the powers and duties to another presiding officer. The substitution will not affect the hearing, except as the new presiding officer may order.

(b) Any motion based on the substitution must be made within 10 days.

Subpart E—Hearing Procedures

§ 12.80 Filing and service of submissions.

(a) Submissions, including pleadings in a hearing, are to be filed with the Dockets Management Branch under § 10.20 except that only two copies need be filed. To determine compliance with filing deadlines in a hearing, a submission is considered submitted on the date it is actually received by the Dockets Management Branch. When this part allows a response to a submission and prescribes a period of time for the filing of the response, an additional 3 days are allowed for the filing of the response if the submission is served by mail.

(b) The person making a submission shall serve copies of it on the other participants. Submissions of documentary data and information are not required to be served on each participant, but any accompanying transmittal letter, pleading, summary, statement of position, certification under paragraph (d) of this section, or similar document must be served on each participant.

(c) Service is accomplished by mailing a submission to the address shown in the notice of participation or by personal delivery.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in § 12.105.

§ 12.82 Petition to participate in forma pauperis.

(a) A participant who believes that compliance with the filing and service requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis.

(b) The petition will be in the form specified in § 10.30 except that the heading will be "Request to Participate in Forma Pauperis, Docket No. ——." Filing and service requirements for the petition are described in paragraph (c) of this section, whether or not the petition is granted. The petition must demonstrate that either: (1) The person is indigent and a strong public interest justifies participation, or (2) the person's participation is in the public interest because it can be considered of primary benefit to the general public.

(c) The Commissioner may grant or deny the petition. If the petition is granted, the participant need file only one copy of each submission with the Dockets Management Branch. The Dockets Management Branch will make sufficient additional copies for the administrative record, and serve a copy on each other participant.

§ 12.83 Advisory opinions.

Before or during a hearing, a person may, under § 10.85, request the Commissioner for an advisory opinion on whether any regulation or order under consideration in the proceeding applies to a specific situation.

§ 12.85 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 12.35, the director of the center responsible for the matters involved in the hearing shall submit the following to the Dockets Management Branch:

(1) The relevant portions of the administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record.

(2) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. "Files" means the principal files in the center in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted.

(3) All other documentary data and information relied upon.

(4) A narrative position statement on the factual issues in the notice of hearing and the type of supporting evidence the director intends to introduce.

(5) A signed statement that, to the director's best knowledge and belief, the submission complies with this section.

(b) Within 60 days of the publication of the notice of hearing or, if no participant will be prejudiced, within another period of time set by the presiding officer, each participant shall submit to the Dockets Management Branch all data and information specified in paragraph (a)(2) through (5) of this section, and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the data and information specified in paragraph (a)(2) of this section, participants shall exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) Submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the presiding officer, upon a showing that the material contained in the supplement was not reasonably known or available when the submission was made or that the relevance of the material contained in the supplement could not reasonably have been forseen.

(d) A participant's failure to comply substantially and in good faith with this section constitutes a waiver of the right to participate further in the hearing; failure of a party to comply constitutes a waiver of the right to a hearing.

(e) Participants may reference each other's submissions. To reduce duplicative submissions, participants are encouraged to exchange and consolidate lists of documentary evidence. If a particular document is bulky or in limited supply and cannot reasonably be reproduced, and it constitutes relevant evidence, the presiding officer may authorize submission of a reduced number of copies.

(f) The presiding officer will rule on questions relating to this section.

[44 FR 22339, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 12.87 Purpose; oral and written testimony; burden of proof.

(a) The objective of a formal evidentiary hearing is the fair determination of relevant facts consistent with the right of all interested persons to participate and the public interest in promptly settling controversial matters affecting the public health and welfare.

(b) Accordingly, the evidence at a hearing is to be developed to the maximum extent through written submissions, including written direct testimony, which may be in narrative or in question-and-answer form.

(1) In a hearing, the issues may have general applicability and depend on general facts that do not concern particular action of a specific party, e.g., the safety or effectiveness of a class of drug products, the safety of a food or color additive, or a definition and standard of identity for a food; or the issues may have specific applicability to past action and depend upon particular facts concerning only that party, e.g., the applicability of a grandfather clause to a particular brand of a drug or the failure of a particular manufacturer to meet required manufacturing and processing specifications or other general standards.

(i) If the proceeding involves general issues, direct testimony will be submitted in writing, except on a showing that written direct testimony is insufficient for a full and true disclosure of relevant facts and that the participant will be prejudiced if unable to present oral direct testimony. If the proceeding involves particular issues, each party may determine whether, and the extent to which, each wishes to present direct testimony orally or in writing.

(ii) Oral cross-examination of witnesses will be permitted if it appears that alternative means of developing the evidence are insufficient for a full and true disclosure of the facts and that the party requesting oral cross-examination will be prejudiced by denial of the request or that oral cross-examination is the most effective and efficient means to clarify the matters at issue.

(2) Witnesses shall give testimony under oath.

(c) Except as provided in paragraph (d) of this section, in a hearing involving issuing, amending, or revoking a regulation or order, the originator of the proposal or petition or of any significant modification will be, within the meaning of 5 U.S.C. 556(d), the proponent of the regulation or order, and will have the burden of proof. A participant who proposes to substitute a new provision for a provision objected to has the burden of proof in relation to the new provision.

(d) At a hearing involving issuing, amending, or revoking a regulation or order relating to the safety or effectiveness of a drug, antibiotic, device, food additive, or color additive, the participant who is contending that the product is safe or effective or both and who is requesting approval or contesting withdrawal of approval has the burden of proof in establishing safety or effectiveness or both and thus the right to approval. The burden of proof remains on that participant in an amendment or revocation proceeding.

§ 12.89 Participation of nonparties.

(a) A nonparty participant may—

(1) Attend all conferences (including the prehearing conference), oral proceedings, and arguments;

(2) Submit written testimony and documentary evidence for inclusion in the record;

(3) File written objections, briefs, and other pleadings; and

(4) Present oral argument.

(b) A nonparty participant may not—

(1) Submit written interrogatories; and

(2) Conduct cross-examination.

(c) A person whose petition is the subject of the hearing has the same right as a party.

(d) A nonparty participant will be permitted additional rights if the presiding officer concludes that the participant's interests would not be adequately protected otherwise or that broader participation is required for a full and true disclosure of the facts, but the rights of a nonparty participant may not exceed the rights of a party.

[44 FR 22339, Apr. 13, 1979, as amended at 48 FR 51770, Nov. 14, 1983]

§ 12.90 Conduct at oral hearings or conferences.

All participants in a hearing will conduct themselves with dignity and observe judicial standards of practice and ethics. They may not indulge in personal attacks, unseemly wrangling, or intemperate accusations or characterizations. Representatives of parties shall, to the extent possible, restrain clients from improprieties in connection with any proceeding. Disrespectful, disorderly, or contumacious language or conduct, refusal to comply with directions, use of dilatory tactics, or refusal to adhere to reasonable standards of orderly and ethical conduct during any hearing, constitute grounds for immediate exclusion from the proceeding by the presiding officer.

§ 12.91 Time and place of prehearing conference.

A prehearing conference will commence at the date, time, and place announced in the notice of hearing, or in a later notice, or as specified by the presiding officer in a notice modifying a prior notice. At that conference the presiding officer will establish the methods and procedures to be used in developing the evidence, determine reasonable time periods for the conduct of the hearing, and designate the times and places for the production of witnesses for direct and cross-examination if leave to conduct oral examination is granted on any issue, as far as practicable at that time.

§ 12.92 Prehearing conference procedure.

(a) Participants in a hearing are to appear at the prehearing conference prepared to discuss and resolve all matters specified in paragraph (b) of this section.

(1) To expedite the hearing, participants are encouraged to prepare in advance for the prehearing conference. Participants should cooperate with each other, and request information and begin preparation of testimony at the earliest possible time. Failure of a participant to appear at the prehearing conference or to raise matters that could reasonably be anticipated and resolved at that time will not delay the progress of the hearing, and constitutes a waiver of the rights of the participant regarding such matters as objections to the agreements reached, actions taken, or rulings issued by the presiding officer and may be grounds for striking the participation under § 12.45.

(2) Participants shall bring to the prehearing conference the following specific information, which will be filed with the Dockets Management Branch under § 12.80:

(i) Any additional information to supplement the submission filed under § 12.85, which may be filed if approved under § 12.85(c).

(ii) A list of all witnesses whose testimony will be offered, orally or in writing, at the hearing, with a full curriculum vitae for each. Additional witnesses may later be identified, with the approval of the presiding officer, on a showing that the witness was not reasonably available at the time of the prehearing conference or the relevance of the witness' views could not reasonably have been foreseen at that time.

(iii) All prior written statements including articles and any written statement signed or adopted, or a recording or transcription of an oral statement made, by persons identified as witnesses if—

(*a*) The statement is available without making request of the witness or any other person;

(*b*) The statement relates to the subject matter of the witness' testimony; and

(*c*) The statement either was made before the time the person agreed to become a witness or has been made publicly available by the person.

(b) The presiding officer will conduct a prehearing conference for the following purposes:

(1) To determine the areas of factual disagreement to be considered at the hearing. The presiding officer may hold conferences off the record in an effort to reach agreement on disputed factual questions.

(2) To identify the most appropriate techniques for developing evidence on issues in controversy and the manner

and sequence in which they will be used, including, where oral examination is to be conducted, the sequence in which witnesses will be produced for, and the time and place of, oral examination. The presiding officer may consider—

(i) Submission of narrative statements of position on factual issues in controversy;

(ii) Submission of evidence or identification of previously submitted evidence to support such statements, such as affidavits, verified statements of fact, data, studies, and reports;

(iii) Exchange of written interrogatories directed to particular witnesses;

(iv) Written requests for the production of additional documentation, data, or other relevant information;

(v) Submission of written questions to be asked by the presiding officer of a specific witness; and

(vi) Identification of facts for which oral examination and/or cross-examination is appropriate.

(3) To group participants with substantially like interests for presenting evidence, making motions and objections, including motions for summary decision, filing briefs, and presenting oral argument.

(4) To hear and rule on objections to admitting into evidence information submitted under § 12.85.

(5) To obtain stipulations and admissions of facts.

(6) To take other action that may expedite the hearing.

(c) The presiding officer shall issue, orally or in writing, a prehearing order reciting the actions taken at the prehearing conference and setting forth the schedule for the hearing. The order will control the subsequent course of the hearing unless modified by the presiding officer for good cause.

§ 12.93 Summary decisions.

(a) After the hearing commences, a participant may move, with or without supporting affidavits, for a summary decision on any issue in the hearing. Any other participant may, within 10 days after service of the motion, which time may be extended for an additional 10 days for good cause, serve opposing affidavits or countermove for summary decision. The presiding officer may set the matter for argument and call for the submission of briefs.

(b) The presiding officer will grant the motion if the objections, requests for hearing, other pleadings, affidavits, and other material filed in connection with the hearing, or matters officially noticed, show that there is no genuine issue as to any material fact and that a participant is entitled to summary decision.

(c) Affidavits should set forth facts that would be admissible in evidence and show affirmatively that the affiant is competent to testify to the matters stated. When a properly supported motion for summary decision is made, a participant opposing the motion may not rest upon mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of fact for the hearing.

(d) Should it appear from the affidavits of a participant opposing the motion that for sound reasons stated, facts essential to justify the opposition cannot be presented by affidavit, the presiding officer may deny the motion for summary decision, order a continuance to permit affidavits or additional evidence to be obtained, or issue other just order.

(e) If on motion under this section a summary decision is not rendered upon the whole case or for all the relief asked, and evidentiary facts need to be developed, the presiding officer will issue an order specifying the facts that appear without substantial controversy and directing further evidentiary proceedings. The facts so specified will be deemed established.

(f) A participant may obtain interlocutory review by the Commissioner of a summary decision of the presiding officer.

§ 12.94 Receipt of evidence.

(a) A hearing consists of the development of evidence and the resolution of factual issues as set forth in this subpart and in the prehearing order.

(b) All orders, transcripts, written statements of position, written direct testimony, written interrogatories and responses, and any other written material submitted in the proceeding is a part of the administrative record of the hearing, and will be promptly placed on public display in the office of the Dockets Management Branch, except as provided in § 12.105.

(c) Written evidence, identified as such, is admissible unless a participant objects and the presiding officer excludes it on objection of a participant or on the presiding officer's own initiative.

(1) The presiding officer may exclude written evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive;

(ii) Exclusion of part or all of the written evidence of a participant is necessary to enforce the requirements of this subpart; or

(iii) The evidence was not submitted as required by § 12.85.

(2) Items of written evidence are to be submitted as separate documents, sequentially numbered, except that a voluminous document may be submitted in the form of a cross-reference to the documents filed under § 12.85.

(3) Written evidence excluded by the presiding officer as inadmissible remains a part of the administrative record, as an offer of proof, for judicial review.

(d) Testimony, whether on direct or on cross-examination, is admissible as evidence unless a participant objects and the presiding officer excludes it.

(1) The presiding officer may exclude oral evidence as inadmissible only if—

(i) The evidence is irrelevant, immaterial, unreliable, or repetitive; or

(ii) Exclusion of part or all of the evidence is necessary to enforce the requirements of this part.

(2) If oral evidence is excluded as inadmissible, the participant may take written exception to the ruling in a brief to the Commissioner, without taking oral exception at the hearing. Upon review, the Commissioner may reopen the hearing to permit the evidence to be admitted if the Commissioner determines that its exclusion was erroneous and prejudicial.

(e) The presiding officer may schedule conferences as needed to monitor the program of the hearing, narrow and simplify the issues, and consider and rule on motions, requests, and other matters concerning the development of the evidence.

(f) The presiding officer will conduct such proceedings as are necessary for the taking of oral testimony, for the oral examination of witnesses by the presiding officer on the basis of written questions previously submitted by the parties, and for the conduct of cross-examination of witnesses by the parties. The presiding officer shall exclude irrelevant or repetitious written questions and limit oral cross-examination to prevent irrelevant or repetitious examination.

(g) The presiding officer shall order the proceedings closed for the taking of oral testimony relating to matters specified in § 10.20(j)(2)(i)(*a*) and (*b*). Such closed proceedings will be conducted in accordance with § 10.20(j)(3). Participation in closed proceedings will be limited to the witness, the witness' counsel, and Federal Government executive branch employees and special government employees. Closed proceedings will be permitted only for, and will be limited to, oral testimony directly relating to matters specified in § 10.20(j)(3).

§ 12.95 Official notice.

(a) Official notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of FDA as an expert agency.

(b) If official notice is taken of a material fact not appearing in the evidence of record, a participant, on timely request, will be afforded an opportunity to show the contrary.

§ 12.96 Briefs and arguments.

(a) Promptly after the taking of evidence is completed, the presiding officer will announce a schedule for the filing of briefs. Briefs are to be filed ordinarily within 45 days of the close of the hearing. Briefs must include a statement of position on each issue, with specific and complete citations to the evidence and points of law relied on. Briefs must contain proposed findings of fact and conclusions of law.

(b) The presiding officer may, as a matter of discretion, permit oral argument after the briefs are filed.

(c) Briefs and oral argument are to refrain from disclosing specific details of written and oral testimony and documents relating to matters specified in § 10.20(j)(2)(i)(*a*) and (*b*), except as specifically authorized in a protective order issued under § 10.20(j)(3).

§ 12.97 Interlocutory appeal from ruling of presiding officer.

(a) Except as provided in paragraph (b) of this section and in §§ 12.35(b), 12.45(e), 12.93(f), and 12.99(d), when an interlocutory appeal is specifically authorized by this subpart, rulings of the presiding officer may not be appealed to the Commissioner before the Commissioner's consideration of the entire record of the hearing.

(b) A ruling of the presiding officer is subject to interlocutory appeal to the Commissioner if the presiding officer certifies on the record or in writing that immediate review is necessary to prevent exceptional delay, expense, or prejudice to any participant, or substantial harm to the public interest.

(c) When an interlocutory appeal is made to the Commissioner, a participant may file a brief with the Commissioner only if specifically authorized by the presiding officer or the Commissioner, and if such authorization is granted, within the period the Commissioner directs. If a participant is authorized to file a brief, any other participant may file a brief in opposition, within the period the Commissioner directs. If no briefs are authorized, the appeal will be presented as an oral argument to the Commissioner. The oral argument will be transcribed. If briefs are authorized, oral argument will be heard only at the discretion of the Commissioner.

§ 12.98 Official transcript.

(a) The presiding officer will arrange for a verbatim stenographic transcript of oral testimony and for necessary copies of the transcript.

(b) One copy of the transcript will be placed on public display in the office of the Dockets Management Branch upon receipt.

(c) Except as provided in § 12.105, copies of the transcript may be obtained by application to the official reporter and payment of costs thereof or under Part 20.

(d) Witnesses, participants, and counsel have 30 days from the time the transcript becomes available to propose corrections in the transcript of oral testimony. Corrections are permitted only for transcription errors. The presiding officer shall promptly order justified corrections.

§ 12.99 Motions.

(a) A motion on any matter relating to the proceeding is to be filed under § 12.80, and must include a draft order, except one made in the course of an oral hearing before the presiding officer.

(b) A response may be filed within 10 days of service of a motion. The time may be shortened or extended by the presiding officer for good cause shown.

(c) The moving party has no right to reply, except as permitted by the presiding officer.

(d) The presiding officer shall rule upon the motion and may certify that ruling to the Commissioner for interlocutory review.

Subpart F—Administrative Record

§ 12.100 Administrative record of a hearing.

(a) The record of a hearing consists of—

(1) The order or regulation or notice of opportunity for hearing that gave rise to the hearing;

(2) All objections and requests for hearing filed by the Dockets Management Branch under §§ 12.20 through 12.22;

(3) The notice of hearing published under § 12.35;

(4) All notices of participation filed under § 12.45;

(5) All Federal Register notices pertinent to the proceeding;

(6) All submissions filed under § 12.82, e.g., the submissions required by § 12.85, all other documentary evidence and written testimony, plead-

ings, statements of position, briefs, and other similar documents;

(7) The transcript, written order, and all other documents relating to the prehearing conference, prepared under § 12.92;

(8) All documents relating to any motion for summary decision under § 12.93;

(9) All documents of which official notice is taken under § 12.95;

(10) All pleadings filed under § 12.96;

(11) All documents relating to any interlocutory appeal under § 12.97;

(12) All transcripts prepared under § 12.98; and

(13) Any other document relating to the hearing and filed with the Dockets Management Branch by the presiding officer or any participant;

(b) The record of the administrative proceeding is closed—

(1) With respect to the taking of evidence, when specified by the presiding officer; and

(2) With respect to pleadings, at the time specified in § 12.96(a) for the filing of briefs.

(c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

§ 12.105 Examination of record.

Documents in the record will be publicly available in accordance with § 10.20(j). Documents available for examination or copying will be placed on public display in the office of the Dockets Management Branch promptly upon receipt in that office.

Subpart G—Initial and Final Decisions

§ 12.120 Initial decision.

(a) The presiding officer shall prepare and file an initial decision as soon as possible after the filing of briefs and oral argument.

(b) The initial decision must contain—

(1) Findings of fact based issued upon relevant, material, and reliable evidence of record;

(2) Conclusions of law;

(3) A discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any participant;

(4) Citations to the record supporting the findings and conclusions;

(5) An appropriate regulation or order supported by substantial evidence of record and based upon the findings of fact and conclusions of law; and

(6) An effective date for the regulation or order.

(c) The initial decision must refrain from disclosing specific details of matters specified in § 10.20(j)(2)(i)(*a*) and (*b*), except as specifically authorized in a protective order issued pursuant to § 10.20(j)(3).

(d) The initial decision is to be filed with the Dockets Management Branch and served upon all participants. Once the initial decision is filed with the Dockets Management Branch, the presiding officer has no further jurisdiction over the matter, and any motions or requests filed with the Dockets Management Branch will be decided by the Commissioner.

(e) The initial decision becomes the final decision of the Commissioner by operation of law unless a participant files exceptions with the Dockets Management Branch under § 12.125(a) or the Commissioner files a notice of review under § 12.125(f).

(f) Notice that an initial decision has become the decision of the Commissioner without appeal to or review by the Commissioner will be published in the FEDERAL REGISTER, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.125 Appeal from or review of initial decision.

(a) A participant may appeal an initial decision to the Commissioner by filing exceptions with the Dockets Management Branch, and serving them on the other participants, within 60 days of the date of the initial decision.

(b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law in the initial decision, and provide supporting citations to the record. Oral argument before the Commissioner may be requested in the exceptions.

(c) Any reply to the exceptions is to be filed and served within 60 days of the end of the period for filing exceptions.

(d) The Commissioner may extend the time for filing exceptions under paragraph (a) of this section or replies to exceptions under paragraph (c) of this section only upon a showing by a participant of extraordinary circumstances. Such an extension shall be requested by filing a written request with the Commissioner's Executive Secretariat (HF-40) and serving copies of the request on the Dockets Management Branch (HFA-305), the Chief Counsel (GCF-1), and all hearing participants.

(e) If the Commissioner decides to hear oral argument, the participants will be informed of the date, time, and place, the amount of time allotted to each participant, and the issues to be addressed.

(f) Within 10 days following the expiration of the time for filing exceptions (including any extensions), the Commissioner may file with the Dockets Management Branch, and serve on the participants, a notice of the Commissioner's determination to review the initial decision. The Commissioner may invite the participants to file briefs or present oral argument on the matter. The time for filing briefs or presenting oral argument will be specified in that or a later notice.

[44 FR 22339, Apr. 13, 1979, as amended at 53 FR 29453, Aug. 5, 1988]

§ 12.130 Decision by Commissioner on appeal or review of initial decision.

(a) On appeal from or review of the initial decision, the Commissioner has all the powers given to make the initial decision. On the Commissioner's own initiative or on motion, the Commissioner may remand the matter to the presiding officer for any further action necessary for a proper decision.

(b) The scope of the issues on appeal is the same as the scope of the issues at the public hearing unless the Commissioner specifies otherwise.

(c) As soon as possible after the filing of briefs and any oral argument, the Commissioner will issue a final decision in the proceeding, which meets the requirements established in § 12.120 (b) and (c).

(d) The Commissioner may adopt the initial decision as the final decision.

(e) Notice of the Commissioner's decision will be published in the FEDERAL REGISTER, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.139 Reconsideration and stay of action.

Following notice or publication of the final decisions, a participant may petition the Commissioner for reconsideration of any part or all of the decision under § 10.33 or may petition for a stay of the decision under § 10.35.

Subpart H—Judicial Review

§ 12.140 Review by the courts.

(a) The Commissioner's final decision constitutes final agency action from which a participant may petition for judicial review under the statutes governing the matter involved. Before requesting an order from a court for a stay of action pending review, a participant shall first submit a petition for a stay of action under § 10.35.

(b) Under 28 U.S.C. 2112(a), FDA will request consolidation of all petitions related to a particular matter.

§ 12.159 Copies of petitions for judicial review.

The Chief Counsel for FDA has been designated by the Secretary as the officer on whom copies of petitions of judicial review are to be served. This officer is responsible for filing the record on which the final decision is based. The record of the proceeding is certified by the Commissioner.

PART 13—PUBLIC HEARING BEFORE A PUBLIC BOARD OF INQUIRY

Subpart A—General Provisions

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13.15 Separation of functions; ex parte communications; administrative support.

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Subpart B—Hearing Procedures

13.20 Submissions to a Board.
13.25 Disclosure of data and information by the participants.
13.30 Proceedings of a Board.

Subpart C—Records of a Hearing Before a Board

13.40 Administrative record of a Board.
13.45 Examination of administrative record.
13.50 Record for administrative decision.

AUTHORITY: Sec. 201 *et seq.*, Pub. L. 717, 52 Stat. 1040 (21 U.S.C. 321 *et seq.*); sec. 1 *et seq.*, Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 *et seq.*); sec. 4. Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 *et seq.*, Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 *et seq.*); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 *et seq.*, Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 *et seq.*); secs. 1-9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1-10, Chapter 358, 29 Stat. 604-609 as amended (21 U.S.C. 41-50); sec. 2 *et seq.*, Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401-411 notes); sec. 1 *et seq.*, Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C 1451 *et seq.*).

SOURCE: 44 FR 22348, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 13.1 Scope.

The procedures in this part apply when—

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to hold a public hearing before a Public Board of Inquiry ("Board") with respect to any matter before FDA;

(b) Under specific sections of this chapter a matter before FDA is subject to a hearing before a Board; or

(c) Under § 12.32, a person who has a right to an opportunity for a formal evidentiary public hearing waives that opportunity and requests that a Board act as an administrative law tribunal concerning the matters involved, and the Commissioner decides to accept this request.

§ 13.5 Notice of a hearing before a Board.

If the Commissioner determines that a Board should be established to conduct a hearing on any matter, a notice of hearing will be published in the FEDERAL REGISTER setting forth the following information:

(a) If the hearing is under § 13.1 (a) or (b), all applicable information described in § 12.32(e).

(1) Any written document that is to be the subject matter of the hearing will be published as a part of the notice, or the notice will refer to it if the document has already been published in the FEDERAL REGISTER or state that the document is available from the Dockets Management Branch or an agency employee designated in the notice.

(2) For purposes of a hearing under § 13.1 (a) or (b), all participants who file a notice of participation under § 12.32(e)(6)(ii) are deemed to be parties and entitled to participate in selection of the Board under § 13.15(b).

(b) If the hearing is in lieu of a formal evidentiary hearing, as provided in § 13.1(c), all of the information described in § 12.32(e).

(Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1 through 9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1 through 10, Chapter 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.); the Agriculture, Rural Development, and Related Agencies Bill (Pub. L. 95-448, 92 Stat. 1073, 1091); and 21 CFR 5.1)

[44 FR 22348, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 13.10 Members of a Board.

(a) All members of a Board are to have medical, technical, scientific, or other qualifications relevant to the issues to be considered, are subject to the conflict of interest rules applicable to special Government employees, and are to be free from bias or prejudice concerning the issues involved. A member of a Board may be a full-time or part-time Federal Government employee or may serve on an FDA advisory committee but, except with the agreement of all parties, may not currently be a full-time or part-time employee of FDA or otherwise act as a special Government employee of FDA.

(b) Within 30 days of publication of the notice of hearing, the director of the center of FDA responsible for a matter before a Board, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, shall each submit to the Dockets Management Branch the names and full curricula vitae of five nominees for members of the Board. Nominations are to state that the nominee is aware of the nomination, is interested in becoming a member of the Board, and appears to have no conflict of interest.

(1) Any two or more persons entitled to nominate members may agree upon a joint list of five qualified nominees.

(2) The lists of nominees must be submitted to the persons entitled to submit a list of nominees under this paragraph but not to all participants. Within 10 days of receipt of the lists of nominees, such persons may submit comments to the Dockets Management Branch on whether the nominees of the other persons meet the criteria established in paragraph (a) of this section. A person submitting comments to the Dockets Management Branch shall submit them to all persons entitled to submit a list of nominees.

(3) The lists of nominees and comments on them are to be held in confidence by the Dockets Management Branch as part of the administrative record of the proceeding and are not to be made available for public disclosure, and all persons who submit or receive them shall similarly hold them in confidence. This portion of the administrative record remains confidential but is available for judicial review in the event that it becomes relevant to any issue before a court.

(c) After reviewing the lists of nominees and any comments, the Commissioner will choose three qualified persons as members of a Board. One member will be from the lists of nominees submitted by the director of the center and by any person whose petition was granted and is the subject of the hearing. The second will be from the lists of nominees submitted by the other parties. The Commissioner may choose the third member from any source. That member is the Chairman of the Board.

(1) If the Commissioner is unable to find a qualified person with no conflict of interest from among a list of nominees or if additional information is needed, the Commissioner will request the submission of the required additional nominees or information.

(2) If a person fails to submit a list of nominees as required by paragraph (b) of this section, the Commissioner may choose a qualified member without further consultation with that person.

(3) The Commissioner will announce the members of a Board by filing a memorandum in the record of the proceeding and sending a copy to all participants.

(d) Instead of using the selection method in paragraphs (b) and (c) of this section, the director of the center, the other parties to the proceeding, and any person whose petition was granted and is the subject of the hearing, may, with the approval of the Commissioner, agree that a standing advisory committee listed in § 14.80 constitutes the Board for a particular proceeding, or that another procedure is to be used for selection of the members of the Board, or that the Board consists of a larger number of members.

(e) The members of a Board serve as consultants to the Commissioner and are special Government employees or Government employees. A Board functions as an administrative law tribunal in the proceeding and is not an advisory committee subject to the requirements of the Federal Advisory Committee Act or Part 14.

(f) The Chairman of the Board has the authority of a presiding officer set out in § 12.70.

[44 FR 22348, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985]

§ 13.15 Separation of functions; ex parte communications; administrative support.

(a) The proceeding of a Board are subject to the provisions of § 10.55 relating to separation of functions and ex parte communications. Representatives of the participants in any proceeding before a Board, including any members of the office of the Chief Counsel of FDA assigned to advise the center responsible for the matter, may have no contact with the members of the Board, except as participants in the proceeding, and may not participate in the deliberations of the Board.

(b) Administrative support for a Board is to be provided only by the office of the Commissioner and the office of the Chief Counsel for FDA.

[44 FR 22348, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

Subpart B—Hearing Procedures

§ 13.20 Submissions to a Board.

(a) Submissions are to be filed with the Dockets Management Branch under § 10.20.

(b) The person making a submission shall serve copies of it on each participant in the proceeding, except as provided in §§ 13.10(b)(2) and 13.45. Submissions of documentary data and information need not be sent to each participant, but any accompanying transmittal letter, summary, statement of position, certification under paragraph (d) of this section, or similar document must be.

(c) A submission must be mailed to the address shown in the notice of appearance or personally delivered.

(d) All submissions are to be accompanied by a certificate of service, or a statement that service is not required.

(e) No written submission or other portion of the administrative record may be held in confidence, except as provided in §§ 13.10(b)(2) and 13.45.

(f) A participant who believes that compliance with the requirements of this section constitutes an unreasonable financial burden may submit to the Commissioner a petition to participate in forma pauperis in the form and manner specified in § 12.82.

§ 13.25 Disclosure of data and information by the participants.

(a) Before the notice of hearing is published under § 13.5, the director of the center responsible for the matters involved in the hearing must submit to the Dockets Management Branch—

(1) The relevant portions of the existing administrative record of the proceeding. Portions of the administrative record not relevant to the issues in the hearing are not part of the administrative record;

(2) A list of all persons whose views will be presented orally or in writing at the hearing;

(3) All documents in the director's files containing factual information, whether favorable or unfavorable to the director's position, which relate to the issues involved in the hearing. "Files" means the principal files in the center in which documents relating to the issues in the hearing are ordinarily kept, e.g., the food additive master file and the food additive petition in the case of issues concerning a food additive, or the new drug application in the case of issues concerning a new drug. Internal memoranda reflecting the deliberative process, and attorney work product and material prepared specifically for use in connection with the hearing, are not required to be submitted;

(4) All other documentary information relied on; and

(5) A signed statement that, to the best of the director's knowledge and belief, the submission complies with this section.

(b) Within the time prescribed in the notice of hearing published under § 13.5, each participant shall submit to the Dockets Management Branch all information specified in paragraph (a)(2) through (5) of this section and any objections that the administrative record filed under paragraph (a)(1) of this section is incomplete. With respect to the information specified in paragraph (a)(3) of this section, participants are to exercise reasonable diligence in identifying documents in files comparable to those described in that paragraph.

(c) The submissions required by paragraphs (a) and (b) of this section may be supplemented later in the proceeding, with the approval of the Board, on a showing that the views of the persons or the material contained in the supplement was not known or reasonably available when the initial submission was made or that the relevance of the views of the persons or the material contained in the supplement could not reasonably have been foreseen.

(d) The failure to comply substantially and in good faith with this section in the case of a participant constitutes a waiver of the right to participate further in the hearing and in the case of a party constitutes a waiver of the right to a hearing.

(e) The Chairman rules on questions relating to this section. Any participant dissatisfied with a ruling may petition the Commissioner for interlocutory review.

[44 FR 22348, Apr. 13, 1979, as amended at 50 FR 8994, Mar. 6, 1985; 54 FR 9035, Mar. 3, 1989]

§ 13.30 Proceedings of a Board.

(a) The purpose of a Board is to review medical, scientific, and technical issues fairly and expeditiously. The proceedings of a Board are conducted as a scientific inquiry rather than a legal trial.

(b) A Board may not hold its first hearing until after all participants have submitted the information required by § 13.25.

(c) The Chairman calls the first hearing of the Board. Notice of the time and location of the first hearing is to be published at least 15 days in advance and the hearing will be open to the public. All participants will have an opportunity at the first hearing to make an oral presentation of the information and views which in their opinion are pertinent to the resolution of the issues being considered by a Board. A participant's presentation may be made by more than one person. The Chairman determines the order of the presentation. Participants may not interrupt a presentation, but members of the Board may ask questions. At the conclusion of a presentation, each of the other participants may briefly comment on the presentation and may request that the Board conduct further questioning on specified matters. Members of the Board may then ask further questions. Any other participant may be permitted to ask questions if the Chairman determines that it will help resolve the issues.

(d) The hearing is informal and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant for any reason.

(e) Within the time specified by the Board after its first hearing, participants may submit written rebuttal information and views in accordance with § 13.20. The Chariman will then schedule a second hearing, if requested and justified by a participant. A second hearing, and any subsequent hearing, will be called only if the Chairman concludes that it is needed to fully and fairly present information that cannot otherwise adequately be considered and to properly resolve the issues. Notice of the time and location of any hearing is to be published at least 15 days in advance. The hearing is open to the public.

(f) A Board may consult with any person who it concludes may have information or views relevant to the issues.

(1) The consultation may occur only at an announced hearing of a Board. Participants have the right to suggest or, with the permission of the Chairman, ask questions of the consultant and present rebuttal information and views, as provided in paragraphs (c) and (d) of this section except that written statements may be submitted to the Board with the consent of all participants.

(2) A participant may submit a request that the Board consult with a specific person who may have information or views relevant to the issues. The request will state why the person should be consulted and why the person's views cannot be furnished to the Board by means other than having FDA arrange for the person's appear-

ance. The Board may, in its discretion, grant or deny the request.

(g) All hearings are to be transcribed. All hearings are open to the public, except that a hearing under § 10.20(j)(3) is closed to all persons except those persons making and participating in the presentation and Federal Government executive branch employees and special Government employees. At least a majority of Board members are to be present at every hearing. The executive sessions of a Board, during which a Board deliberates on the issues, are to be closed and are not transcribed. All members of the Board shall vote on the report of the Board.

(h) All legal questions are to be referred to the Chief counsel for FDA for resolution. The Chief Counsel's advice on any matter of procedure or legal authority is to be transmitted in writing and made a part of the record or presented in open session and transcribed.

(i) At the conclusion of all public hearings the Board will announce that the record is closed to receiving information. The Board will provide an opportunity for participants to submit written statements of their positions, with proposed findings and conclusions, and may in its discretion, provide an opportunity for participants to summarize their positions orally.

(j) The Board will prepare a decision on all issues. The decision is to include specific findings and references supporting and explaining the Board's conclusions, and a detailed statement of the reasoning on which the conclusions are based. Any member of the Board may file a separate report stating additional or dissenting views.

Subpart C—Records of a Hearing Before a Board

§ 13.40 Administrative record of a Board.

(a) The administrative record of a hearing before a Board consists of the following:

(1) All relevant FEDERAL REGISTER notices.

(2) All written submissions under § 13.20.

(3) The transcripts of all hearings of the Board.

(4) The initial decision of the Board.

(b) The record of the administrative proceeding is closed—

(1) Relevant to receiving information and data, at the time specified in § 13.30(i); and

(2) Relevant to pleadings, at the time specified in § 13.30(i) for filing a written statement of position with proposed findings and conclusions.

(c) The Board may, in its discretion, reopen the record to receive further evidence at any time before filing an initial decision.

§ 13.45 Examination of administrative record.

(a) The availability for public examination and copying of each document which is a part of the administrative record of the hearing is governed by § 10.20(j). Each document available for public examination or copying is placed on public display in the office of the Dockets Management Branch promptly upon receipt in that office.

(b) Lists of nominees and comments submitted on them under § 13.10(b)(3) are not subject to disclosure unless they become an issue in a court proceeding.

§ 13.50 Record for administrative decision.

The administrative record of the hearing specified in § 13.40(a) constitutes the exclusive record for decision.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

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AUTHORITY: 5 U.S.C. 5332 note; 15 U.S.C. 1451 et seq.; 21 U.S.C. 41 et seq.; 141 et seq., 321-371, 467f(b), 679(b), 821, 1031 et seq.; 42 U.S.C. 201 et seq.; 257a; 21 CFR 5.10.

SOURCE: 44 FR 22351, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 14.1 Scope.

(a) This part governors the procedures when any of the following applies:

(1) The Commissioner concludes, as a matter of discretion, that it is in the public interest for a standing or ad hoc policy or technical public advisory committee ("advisory committee" or "committee") to hold a public hearing and to review and make recommendations on any matter before FDA and for interested persons to present information and views at an oral public hearing before the advisory committee.

(2) Under specific provisions in the act or other sections of this chapter, a matter is subject to a hearing before an advisory committee. The specific provisions are—

(i) Section 14.120 on review of a performance standard for an electronic product by the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC);

(ii) Section 14.140 on review of the safety of color additives;

(iii) Section 14.160 on review of the safety and effectiveness of human prescription drugs;

(iv) Section 330.10 on review of the safety and effectiveness of over-the-counter drugs;

(v) Section 601.25 on review of the safety and effectiveness of biological drugs;

(vi) Part 860, on classification of devices;

(vii) Section 514(g)(5) of the act on establishment, amendment, or revocation of a device performance standard;

(viii) Section 515 of the act on review of device premarket approval applications and product development protocols; and

(ix) Section 520(f) of the act on review of device good manufacturing practice regulations.

(3) A person who has a right to an opportunity for a formal evidentiary public hearing under Part 12 waives that opportunity and instead under § 12.32 requests a hearing before an advisory committee, and the Commissioner, as a matter of discretion, accepts the request.

(b) In determining whether a group is a "public advisory committee" as defined in § 10.3(a) and thus subject to this part and to the Federal advisory Committee Act, the following guidelines will be used:

(1) An advisory committee may be a standing advisory committee or an ad hoc advisory committee. All standing advisory committees are listed in § 14.100.

(2) An advisory committee may be a policy advisory committee or a technical advisory committee. A policy advisory committee advises on broad and general matters. A technical advisory committee advises on specific technical or scientific issues, which may relate to regulatory decisions before FDA.

(3) An advisory committee includes any of its subgroups when the subgroup is working on behalf of the committee. Section 14.40(d) describes when a subgroup will be established as an advisory committee separate from the parent committee.

(4) A committee composed entirely of full-time Federal Government employees is not an advisory committee.

(5) An advisory committee ordinarily has a fixed membership, a defined purpose of providing advice to the agency on a particular subject, regular or periodic meetings, and an organizational structure, for example, a chairman and staff, and serves as a source of independent expertise and advice rather than as a representative of or advocate for any particular interest. The following groups are not advisory committees:

(i) A group of persons convened on an ad hoc basis to discuss a matter of current interest to FDA, but which has no continuing function or organization and does not involve substantial special preparation.

(ii) A group of two or more FDA consultants meeting with the agency on an ad hoc basis.

(iii) A group of experts who are employed by a private company or a trade association which has been requested by FDA to provide its views on a regulatory matter pending before FDA.

(iv) A consulting firm hired by FDA to provide advice regarding a matter.

(6) An advisory committee that is utilized by FDA is subject to this subpart even though it was not established by FDA. In general, a committee is "utilized" when FDA requests advice or recommendations from the committee on a specific matter in order to obtain an independent review and consideration of the matter, and not when FDA is merely seeking the comments of all interested persons or of persons who have a specific interest in the matter.

(i) A committee formed by an independent scientific or technical organization is utilized if FDA requests advice of that committee rather than of the parent organization, or if the circumstances show that the advice given is that of the committee and not of the parent organization. A committee formed by an independent scientific or technical organization is not utilized if FDA requests advice of the organization rather than of a committee and if the recommendations of any committee formed in response to the request are subject to substantial independent policy and factual review by the governing body of the parent organization.

(ii) A committee is not utilized by FDA if it provides only information, as contrasted with advice or opinions or recommendations.

(iii) FDA is charged with seeking out the views of all segments of the public on enforcement of the laws administered by the Commissioner. The fact that a group of individuals or a committee meets regularly with FDA, for example, a monthly meeting with consumer representatives, does not make that group or committee an advisory committee. Thus, this subpart does not apply to routine meetings, discussions, and other dealings, including exchanges of views, between FDA and any committee representing or advocating the particular interests of consumers, industry, professional organizations, or others.

(7) The inclusion of one or two FDA consultants who are special Government employees on an internal FDA committee does not make that committee an advisory committee.

(8) A Public Board of Inquiry established under Part 13, or other similar group convened by agreement between the parties to a regulatory proceeding pending before FDA to review and prepare an initial decision on the issues in lieu of a formal evidentiary public hearing, is acting as an administrative law tribunal and is not an advisory committee.

(9) An open public conference or meeting conducted under § 10.65(b) is not an advisory committee meeting.

(10) An FDA committee that primarily has operational responsibility rather than that of providing advice and recommendations is not an advisory committee, for example, the Research Involving Human Subjects Committee (RIHSC).

(c) This part applies only when a committee convenes to conduct committee business. Site visits, social gatherings, informal discussions by telephone or during meals or while traveling or at other professional functions, or other similar activities do not constitute a meeting.

(d) An advisory committee that is utilized but not established by FDA is subject to this part only to the extent of such utilization, and not concerning any other activities of such committee.

(e) Any conference or meeting between an employee of FDA and a committee or group which is not an advisory committee shall be subject to § 10.65 or other provisions specifically applicable to the committee or group, for example, Part 13 for a Public Board of Inquiry.

(f) This part applies to all FDA advisory committees, except to the extent that specific statutes require otherwise for a particular committee, for example, TEPRSSC, the Board of Tea Experts, and advisory committees established under the Medical Device Amendments of 1976.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 14.5 Purpose of proceedings before an advisory committee.

(a) An advisory committee is utilized to conduct public hearings on matters of importance that come before FDA, to review the issues involved, and to provide advice and recommendations to the Commissioner.

(b) The Commissioner has sole discretion concerning action to be taken and policy to be expressed on any matter considered by an advisory committee.

§ 14.7 Administrative remedies.

A person who alleges noncompliance by the Commissioner or an advisory committee with any provision of this part or the Federal Advisory Committee Act may pursue the following administrative remedies:

(a) If the person objects to any action, including a failure to act, other than denial of access to an advisory committee document, the person shall submit a petition in the form and in accordance with the requirements of § 10.30. The provisions of § 10.45 relating to exhaustion of administrative remedies are applicable.

(1) If the person objects to past action, the person shall submit the pe-

tition within 30 days after the action objected to. If the Commissioner determines that there was noncompliance with any provision of this subpart or of the Federal Advisory Committee Act, the Commissioner will grant any appropriate relief and take appropriate steps to prevent its future recurrence.

(2) If the person objects to proposed future action, the Commissioner will expedite the review of the petition and make a reasonable effort to render a decision before the action concerned in the petition.

(3) If the person objects to action that is imminent or occurring and which could not reasonably have been anticipated, e.g., the closing of a portion of a meeting which is made known for the first time on the day of the meeting, the matter may be handled by an oral petition in lieu of a written petition.

(b) If the person objects to a denial of access to an advisory committee document, administrative review is in accordance with the procedures established by the Department of Health and Human Services under 45 CFR 5.82.

§ 14.10 Applicability to Congress.

This part applies to Congress, individual Members of Congress, and other employees or representatives of Congress in the same way that they apply to any other member of the public, except that disclosure of advisory committee records to Congress is governed by § 20.87.

§ 14.15 Committees working under a contract with FDA.

(a) FDA may enter into contracts with independent scientific or technical organizations to obtain advice and recommendations on particular matters, and these organizations may in turn undertake such work through existing or new committees. Whether a particular committee working under such a contract is an advisory committee subject to the Federal Advisory Committee Act and this subpart depends upon application of the criteria and principles in § 14.1(b).

(b) The following minimum standards apply to any committee of an independent scientific or technical organization which is working under a contract initially executed with FDA after July 1, 1975, but which is determined not to be an advisory committee:

(1) The committee shall give public notice of its meetings and agenda, and provide interested persons an opportunity to submit relevant information and views in writing at any time, and orally at specified times. The notice may be published in the FEDERAL REGISTER or disseminated by other reasonable means. It is in any event to be filed with the Dockets Management Branch not less than 15 days before the meeting. The time for oral presentations and the extent to which the committee meets in open session other than for such oral presentations is in the discretion of the committee.

(2) Minutes of open sessions are to be maintained, with all written submissions attached which were made to the committee in open session. After approval, the minutes are to be forwarded to the Dockets Management Branch and placed on public display. The extent to which the committee maintains minutes of closed sessions is in the discretion of the committee.

(3) In selecting the members of the committee, the organization involved is to apply the principles relating to conflicts of interest that FDA uses in establishing a public advisory committee. Those principles are set out or cross-referenced in this part and in Part 19. Upon request, FDA will assist or provide guidance to any organization in meeting this requirement.

Subpart B—Meeting Procedures

§ 14.20 Notice of hearing before an advisory committee.

(a) Before the first of each month, and at least 15 days in advance of a meeting, the Commissioner will publish a notice in the FEDERAL REGISTER of all advisory committee meetings to be held during the month. Any advisory committee meetings for that month called after the publication of the general monthly notice are to be announced in the FEDERAL REGISTER on an individual basis at least 15 days in advance. The Commissioner may authorize an exception to these notice requirements in an emergency or for other reasons requiring an immediate meeting of an advisory committee, in which case public notice will be given at the earliest time and in the most accessible form feasible including, whenever possible, publication in the FEDERAL REGISTER.

(b) The FEDERAL REGISTER notice will include—

(1) The name of the committee;

(2) The date, time, and place of the meeting;

(3) The general function of the committee;

(4) A list of all agenda items, showing whether each will be discussed in an open or closed portion of the meeting;

(5) If any portion of the meeting is closed, a statement of the time of the open and closed portions;

(6) The nature of the subjects to be discussed during, and the reasons for closing, any closed portion of the meeting;

(7) The time set aside for oral statements and other public participation;

(8) The name, address, and telephone number of the advisory committee executive secretary and any other agency employee designated as responsible for the administrative support for the advisory committee;

(9) A statement that written submissions may be made to the advisory committee through the executive secretary at any time, unless a cutoff date has been established under § 14.35(d)(2);

(10) When a notice is published in the FEDERAL REGISTER less than 15 days before a meeting, an explanation for the lateness of the notice; and

(c) If a public hearing before an advisory committee is used in lieu of a formal evidentiary public hearing under § 14.1(a)(3), an initial notice of hearing is to be published separately in the FEDERAL REGISTER containing all the information described in § 12.32(e). This procedure may be used for any other hearing before an advisory committee when the Commissioner concludes, as a matter of discretion, that it would be informative to the public.

(d) A list of advisory committee meetings will be distributed to the press by the Associate Commissioner for Public Affairs.

(e) All advisory committee meetings are to be included on the public calendar described in § 10.100(a).

[44 FR 22351, Apr. 13, 1979, as amended at 47 FR 26375, June 1, 1982; 54 FR 9035, Mar. 3, 1989]

§ 14.22 Meetings of an advisory committee.

(a) No advisory committee may conduct a meeting except at the call or with the advance approval of, and with an agenda approved by, the designated Federal employee or alternate. No meeting may be held in the absence of the designated Federal employee.

(1) If any matter is added to the agenda after its publication in the FEDERAL REGISTER under § 14.20(b)(4), an attempt is to be made to inform persons known to be interested in the matter, and the change is to be announced at the beginning of the open portion of the meeting.

(2) The advisory committee meeting is to be conducted in accordance with the approved final agenda insofar as practical.

(b) Advisory committee meetings will be held at places that are reasonably accessible to the public. All advisory committee meetings will be held in Washington, DC, or Rockville, MD, or the immediate vicinity, unless the Commissioner receives and approves a written request from the advisory committee for a different location. A different location may be approved when one or more of the following applies:

(1) The total cost of the meeting to the Government will be reduced.

(2) A substantial number of the committee members will be at the location at no expense to FDA for other reasons, e.g., for a meeting of a professional association.

(3) It is a central location more readily accessible to committee members.

(4) There is a need for increased participation available at that location.

(5) The committee wishes to review work or facilities in a specific location.

(6) The committee is concerned with matters that functionally or historically occur in some other location, e.g., the Board of Tea Experts and the Science Advisory Board of the National Center for Toxicological Research will generally hold meetings in Brooklyn, N.Y., and in the Little Rock, Ark., vicinity, respectively.

(c) Advisory committee members may, with the approval of FDA, conduct onsite visits relevant to their work.

(d) Unless the committee charter provides otherwise, a quorum for an advisory committee is a majority of the current voting members of the committee, except as provided in § 14.125(c) for TEPRSSC. Any matter before the advisory committee is to be decided by a majority vote of the voting members present at the time, except that the designated Federal official may require that any final report be voted upon by all current voting members of the committee. Any current voting member of the committee may file a separate report with additional or minority views.

(e) If space is available, any interested person may attend any portion of any advisory committee meeting which is not closed.

(f) Whenever feasible, meetings are to be held in government facilities or other facilities involving the least expense to the public. The size of the meeting room is to be reasonable, considering such factors as the size of the committee, the number of persons expected to attend a meeting, and the resources and facilities available.

(g) The Commissioner may authorize a meeting to be held by conference telephone call. For these meetings, a speaker phone will be provided in a conference room located in Washington, D.C., or Rockville, Md., or the immediate vicinity, to permit public participation in open portions of the meetings, as provided in §§ 14.25 and 14.29. These meetings generally will be brief, and authorized—

(1) For the purpose of taking final votes or otherwise confirming actions taken by the committee at other meetings; or

(2) Where time does not permit a meeting to be held at a central location.

(h) Any portion of a meeting will be closed by the committee chairman only when matters are to be discussed which the Commissioner has determined may be considered in closed session under § 14.27(b). If a portion of the meeting is closed, the closed portion will be held after the conclusion of the open portion whenever practicable.

(i) Any committee member may take notes during meetings and report and discuss committee deliberations after a meeting is completed and before official minutes or a report are available, within the rules and regulations adopted by FDA and by the advisory committee with the concurrence of FDA, including all of the following:

(1) There may be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There may be no reporting or discussion of any particular matter if the committee or FDA specifically so directs, e.g., where deliberations are incomplete or involve a sensitive regulatory decision that requires preparation or implementation.

(3) There may be no reporting or discussion of information prohibited from public disclosure under § 14.75.

(4) Notes or minutes kept or reports prepared by a committee member have no status or effect unless adopted into the official minutes or report by the committee. It is the responsibility of each committee member to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting the committee member attended.

[44 FR 22351, Apr. 13, 1979; 48 FR 40887, Sept. 12, 1983, as amended at 54 FR 9035, Mar. 3, 1989]

§ 14.25 Portions of advisory committee meetings.

An advisory committee meeting has the following portions:

(a) *The open public hearing.* Every committee meeting includes an open portion, which constitutes a public hearing during which interested persons may present relevant information or views orally or in writing. The hearing is conducted in accordance with § 14.29.

(b) *The open committee discussion.* A committee discusses any matter pending before it in an open portion of its meeting unless the meeting has been closed for that matter under § 14.27. To the maximum extent feasible, consistent with the policy expressed in § 14.27, a committee conducts its discussion of pending matters in an open portion. No public participation is permissible during this portion of the meeting except with the consent of the committee chairman.

(c) *The closed presentation of data.* Information prohibited from public disclosure under Part 20 and the regulations referenced therein is presented to the committee in a closed portion of its meeting. However, if information is in the form of a summary that is not prohibited from public disclosure, the presentation is to be made in an open portion of a meeting.

(d) *The closed committee deliberations.* Deliberations about matters before an advisory committee may be held in a closed portion of a meeting only upon an appropriate determination by the Commissioner under § 14.27.

§ 14.27 Determination to close portions of advisory committee meetings.

(a) No committee meeting may be entirely closed. A portion of a meeting may be closed only in accordance with a written determination by the Commissioner under this section.

(b) The executive secretary or other designated agency employee shall prepare the initial request for a determination to close a portion of a meeting, specifying the matter(s) to be discussed during the closed portion and the reasons why the portion should be closed. The Commissioner, based upon this request and with the concurrence of the Chief Counsel, will determine whether to close a portion of a meeting. The reasons for closing a portion of a meeting will be announced in the Federal Register notice of the meeting under § 14.20 in accordance with the following rules:

(1) Any determination to close a portion of a meeting restricts the closing to the shortest possible time consistent with the policy in this section.

(2) A portion of a meeting may be closed only if the Commissioner determines that the closing is permitted under 5 U.S.C. 552b(c), and that the closing is necessary.

(3) Portions of meetings may ordinarily be closed if they concern the review, discussion, and evaluation of drafts or regulations, guidelines or similar preexisting internal agency documents, but only if their premature disclosure would significantly impede proposed agency action; review of trade secrets and confidential commercial or financial information; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(4) Portions of meetings ordinarily may not be closed if they concern review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs and devices; review of information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other information not exempt from public disclosure under 5 U.S.C. 552b(c); the formulation of advice and recommendations to FDA on matters that do not independently justify closing.

(5) No portion of a meeting devoted to matters other than those designated in paragraph (b) (1) through (3) of this section may be closed.

(6) A matter which is properly considered in an open portion of a meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise the matters to be discussed in the closed portion.

(c) Attendance at a closed portion of a meeting is governed by the following rules:

(1) A portion of a meeting closed for the presentation or discussion of information that constitutes a trade secret or confidential commercial or financial information as defined in § 20.61 may be attended only by voting advisory committee members, nonvoting members representing consumer interests who are also special government employees as provided in § 14.80(b), the executive secretary of the advisory committee, a transcriber, consultants, and such other regular employees of FDA (including members of the Office of the Chief Counsel) as the chairman of the advisory committee may invite, and by those persons authorized to be present under § 14.25.(c), for presentation of information prohibited from public disclosure. A person making a presentation described in § 14.25(c) may be accompanied by a reasonable number of employees, consultants, or other persons in a commercial arrangement within the meaning of § 20.81(a).

(2) A portion of a meeting that has been closed for consideration of existing internal agency documents falling within § 20.62 where premature disclosure is likely to significantly impede proposed agency action; personnel, medical, and similar files, disclosure of which would be a clearly unwarranted invasion of personal privacy within the meaning of § 20.63; or investigatory records compiled for law enforcement purposes as defined in § 20.64 may be attended only by committee members (voting and nonvoting), the executive secretary of the committee, a transcriber, and other regular employees of FDA (including members of the Office of the Chief Counsel) whom the chairman of the committee may invite. Consultants, individuals performing personal service contracts, employees of other Federal agencies, and the general public may not attend such portions.

(3) If a person other than a person permitted to attend in accordance with paragraph (c) (1) and (2) of this section attempts to attend a closed portion of a meeting without the approval of the executive secretary and the chairman, and the matter is brought to their attention, the person will be required to leave the meeting immediately. This inadvertent and unauthorized attendance does not enable other unauthorized persons to attend, nor does it, of itself, constitute grounds for release of transcripts of closed portions or any other documents otherwise exempt from disclosure under § 14.75 and Part 20.

(4) If a person other than a person permitted to attend in accordance with paragraphs (c) (1) and (2) of this section is allowed by the executive secretary and the chairman to attend a closed portion of a meeting, that portion is open to attendance by any interested person.

§ 14.29 Conduct of a hearing before an advisory committee.

(a) For each meeting, the open portion for public participation, which constitutes a public hearing under § 14.25(a), will be at least 1 hour, unless public participation does not last that long, and may last for whatever longer time the committee chairman determines will facilitate the work of the committee. The FEDERAL REGISTER notice published under § 14.20 will designate the time specifically reserved for the hearing, which is ordinarily the first portion of the meeting. Further public participation in any open portion of the meeting under § 14.25(b) is solely at the discretion of the chairman.

(b) An interested person who wishes to be assured of the right to make an oral presentation at a meeting shall inform the executive secretary or other designated agency employee, orally or in writing, before the meeting.

(1) The person shall state the general nature of the presentation and the approximate time desired. Whenever possible, all written information to be discussed by that person at the meeting should be furnished in advance to the executive secretary or other designated agency employee. This material may be distributed or mailed by FDA to the committee members in advance of the meeting if time permits, and otherwise will be distributed to the members when they arrive for the meeting. The mailing or distribution may be undertaken only by FDA

unless FDA grants permission to a person to mail or distribute the material

(2) Before the meeting, the executive secretary or other designated agency employee shall determine the amount of time allocated to each person for oral presentation and the time that the presentation is to begin. Each person will be so informed in writing, if time permits, or by telephone. FDA may require persons with common interests to make joint presentations.

(c) The chairman of the committee shall preside at the meeting in accordance with § 14.30 and be accompanied by other committee members, who serve as a panel in conducting the hearing portion of the meeting.

(d) Each person may use the allotted time as desired, consistent with an orderly hearing. A person may be accompanied by additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 14.35(c).

(e) If a person is absent at the time specified for that person's presentation, the persons following will appear in order. An attempt will be made to hear the person at the conclusion of the hearing. Interested persons attending the hearing who did not request an opportunity to make an oral presentation may be given an opportunity to do so at the discretion of the chairman.

(f) The chairman and other members may question a person concerning that person's presentation. No other person, however, may question the person. The chairman may allot additional time when it is in the public interest, but may not reduce the time allotted without consent of the person.

(g) Participants may question a committee member only with that member's permission and only about matters before the committee.

(h) The hearing is informal, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut matters presented. No participant may interrrupt the presentation of another participant.

§ 14.30 Chairman of an advisory committee.

(a) The advisory committee chairman has the authority to conduct hearings and meetings, including the authority to adjourn a hearing or meeting if the chairman determines that adjournment is in the public interest, to discontinue discussion of a matter, to conclude the open portion of a meeting, or to take any other action to further a fair and expeditious hearing or meeting.

(b) If the chairman is not a full-time employee of FDA, the executive secretary or other designated agency employee, or alternate, is to be the "designated Federal employee" who is assigned to the advisory committee. The designated Federal employee is also authorized to adjourn a hearing or meeting if the employee determines adjournment to be in the public interest.

§ 14.31 Consultation by an advisory committee with other persons.

(a) A committee may confer with any person who may have information or views relevant to any matter pending before the committee.

(b) An interested person may submit to the committee a written request that it confer with specific persons about any matter pending before the committee. The request is to contain adequate justification. The committee may, in its discretion, grant the request.

(c) A committee may confer with a person who is not a Federal Government executive branch employee only during the open portions of a meeting. The person may, however, submit views in writing to the committee as part of the administrative record under § 14.70. The person may participate at the closed portions of a meeting only if appointed as a special Government employee by the Commissioner as provided in paragraph (e) of this section. This paragraph (c) is not intended to bar the testimony of a person during a closed portion of a meeting about matters prohibited from public disclosure under §§ 14.25(c) and 14.27(c).

(d) To prevent inadvertent violation of Federal conflict of interest laws and laws prohibiting disclosure of trade secrets (18 U.S.C. 208, 21 U.S.C. 331(j), 18 U.S.C. 1905), Federal executive branch employees who are not employees of the Department may not confer, testify, or otherwise participate (other than as observers) at any portion of an advisory committee meeting unless they are appointed as special Government employees by the Commissioner under paragraph (e) of this section. this paragraph does not apply to Federal executive branch employees who are appointed as members of TEPRSSC, as provided in § 14.127.

(e) The Commissioner may appoint persons as special Government employees to be consultants to an advisory committee. Consultants may be appointed to provide expertise, generally concerning a highly technical matter, not readily available from the members of the committee. Consultants may be either from outside the Government or from agencies other than the Department of Health and Human Services. Reports, data, information, and other written submissions made to a public advisory committee by a consultant are part of the administrative record itemized in § 14.70.

§ 14.33 Compilation of materials for members of an advisory committee.

The Commissioner shall prepare and provide to all committee members a compilation of materials bearing upon members' duties and responsibilities, including—

(a) All applicable conflict of interest laws and regulations and a summary of their principal provisions;

(b) All applicable laws and regulations relating to trade secrets and confidential commercial or financial information that may not be disclosed publicly and a summary of their principal provisions;

(c) All applicable laws, regulations, and guidelines relating to the subject matter covered by the advisory committee and a summary of their principal provisions;

(d) All applicable laws, regulations, including the regulations in Part 20 of this chapter, advisory committee charters, FEDERAL REGISTER notices, curricula vitae, rules adopted by the advisory committee, and other material relating to the formation, composition, and operation of the advisory committee, and a summary of their principal provisions;

(e) Instructions on whom to contact when questions arise; and

(f) Other material relating to FDA and the subject matter covered by the committee which may facilitate the work of the committee.

§ 14.35 Written submissions to an advisory committee.

(a) Ten copies of written submissions to a committee are to be sent to the executive secretary unless an applicable FEDERAL REGISTER notice or other regulations in this chapter specify otherwise. Submissions are subject to the provisions of § 10.20, except that it is not necessary to send copies to the Dockets Management Branch.

(b) At the request of a committee, or on the Commissioner's own initiative, the Commissioner may issue in the FEDERAL REGISTER a notice requesting the submission to the committee of written information and views pertinent to a matter being reviewed by the committee. The notice may specify the manner in which the submission should be made.

(c) At the request of a committee, or on the Commissioner's own initiative, the Commissioner may at any time request the applicant or sponsor of an application or petition about a specific product on which action is pending before FDA, and is being reviewed by an advisory committee, to present or discuss safety, effectiveness, or other data concerning the product during a regularly scheduled meeting of the committee. The request may be for an oral presentation or for a concise, well-organized written summary of pertinent information for review by the committee members before the meeting, or both. Unless specified otherwise, one copy of the written summary along with a proposed agenda outlining the topics to be covered and identifying the participating industry staff members or consultants that will present each topic is to be submitted to the executive secretary or other designated agency employee at least 3 weeks before the meeting.

(d) An interested person may submit to a committee written information or views on any matter being reviewed. Voluminous data is to be accompanied by a summary. A submission is to be made to the executive secretary and not directly to a committee member.

(1) FDA will distribute submissions to each member, either by mail or at the next meeting. Submissions will be considered by the committee in its review of the matter.

(2) A committee may establish, and give public notice of, a cutoff date after which submissions about a matter will no longer be received or considered.

(e) The Commissioner will provide the committee all information the Commissioner deems relevant. A member will, upon request, also be provided any material available to FDA which the member believes appropriate for an independent judgment on the matter, e.g., raw data underlying a summary or report, or a briefing on the legal aspects of the matter.

§ 14.39 Additional rules for a particular advisory committee.

(a) In addition to these rules, an advisory committee may, with the concurrence of the designated Federal employee, adopt additional rules which are not inconsistent with this subpart or with other legal requirements.

(b) Any additional rules will be included in the minutes of the meeting when adopted and in the materials compiled under § 14.33 and will be available for public disclosure under § 14.65(c).

Subpart C—Establishment of Advisory Committees

§ 14.40 Establishment and renewal of advisory committees.

(a) An advisory committee may be established or renewed whenever it is necessary or appropriate for the committee to hold a public hearing and to review and make recommendations on any matter pending before FDA. Except for committees established by statute, before a committee is established or renewed it must first be approved by the Department pursuant to 45 CFR Part 11 and by the General Services Administration.

(b) When an advisory committee is established or renewed, the Commissioner will issue a FEDERAL REGISTER notice certifying that the establishment or renewal is in the public interest and stating the structure, function, and purposes of the committee and, if it is a standing advisory committee, shall amend § 14.100 to add it to the list of standing advisory committees. The notice will be published at least 15 days before the filing of the advisory committee charter under paragraph (c) of this section.

(c) No committee may meet or take action until its charter is prepared and filed as required by section 9(c) of the Federal Advisory Committee Act. This requirement is to be met by an advisory committee utilized by FDA, even though it is not established by the agency, prior to utilization.

(d) The regulations of the Department cited in paragraph (a) of this section provide that the charter of a parent committee may incorporate information concerning activities of a subgroup. In such instances, a subgroup will not be established as a committee distinct from the parent committee. However, a subgroup will be established as a separate committee when the charter of the parent committee does not incorporate the activities of the subgroup, or when the subgroup includes members who are not all drawn from the parent committee.

(e) An advisory committee not required to be established by law will be established or utilized only if it is in the public interest and only if its functions cannot reasonably be performed by other existing advisory committees or by FDA.

(f) An advisory committee must meet the following standards:

(1) Its purpose is clearly defined.

(2) Its membership is balanced fairly in terms of the points of view represented in light of the functions to be performed. Although proportional representation is not required, adviso-

ry committee members are selected without regard to race, color, national origin, religion, age, or sex.

(3) It is constituted and utilizes procedures designed to assure that its advice and recommendations are the result of the advisory committee's independent judgment.

(4) Its staff is adequate. The Commissioner designates an executive secretary and alternate for every advisory committee, who are employees of FDA. The executive secretary is responsible for all staff support unless other agency employees are designated for this function.

(5) Whenever feasible, or required by statute, it includes representatives of the public interest.

§ 14.55 Termination of advisory committees.

(a) Except as provided in paragraph (c) of this section, a standing advisory committee is terminated when it is no longer needed, or not later than 2 years after its date of establishment unless it is renewed for an additional 2-year period. A committee may be renewed for as many 2-year periods as the public interest requires. The requirements for establishment of a committee under § 14.40 also apply to its renewal.

(b) FDA will issue a FEDERAL REGISTER notice announcing the reasons for terminating a committee and, if it is a standing committee, amending § 14.100 to delete it from the list.

(c) TEPRSSC is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act (42 U.S.C. 263f(f)(1)(A), as added by the Radiation Control for Health and Safety Act of 1968, and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c). Also, the statutory medical device classification panels established under section 513(b)(1) of the act and Part 860, and the statutory medical device good manufacturing practice advisory committees established under section 520(f)(3) of the act, are specifically exempted from the normal 2-year duration period.

(d) The Board of Tea Experts is a permanent statutory advisory committee established by the Tea Importation Act (21 U.S.C. 42) and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c).

(e) Color additive advisory committees are required to be established under the circumstances specified in section 706(b)(5) (C) and (D) of the act. A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of this part.

Subpart D—Records of Meetings and Hearings Before Advisory Committees

§ 14.60 Minutes and reports of advisory committee meetings.

(a) The executive secretary or other designated agency employee prepares detailed minutes of all advisory committee meetings, except that less detailed minutes may be prepared for open portions of meetings which under § 14.61, must be transcribed or recorded by the agency. Their accuracy is approved by the committee and certified by the chairman. The approval and certification may be accomplished by mail or by telephone.

(b) The minutes include the following:

(1) The time and place of the meeting.

(2) The members, committee staff, and agency employees present, and the names and affiliations or interests of public participants.

(3) A copy of or reference to all written information made available for consideration by the committee at the proceedings.

(4) A complete and accurate description of matters discussed and conclusions reached. A description is to be kept separately for the following portions of the meeting to facilitate their public disclosure: The open portions specified in § 14.25 (a) and (b), any closed portion during which a presentation is made under § 14.25(c), and

any closed deliberative portion under § 14.25(d). The minutes of a closed deliberative portion of a meeting may not refer to members by name, except upon their request, or to data or information described in § 14.75(b). Any inadvertent references that occur are to be deleted before public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the committee.

(6) The extent to which the meeting was open to the public.

(7) The extent of public participation, including a list of members of the public who presented oral or written statements.

(c) For a meeting that has a closed portion, either (1) the minutes of the closed portion are available for public disclosure under § 14.75(a)(6)(i), or (2) if under § 14.75(a)(6)(ii) they are not promptly available, the executive secretary or other designated agency employee shall prepare a brief summary of the matters considered in an informative manner to the public, consistent with 5 U.S.C. 552(b).

(d) Where a significant portion of the meeting of a committee is closed, the committee will issue a report at least annually setting forth a summary of its activities and related matters informative to the public consistent with 5 U.S.C. 552(b). This report is to be a compilation of or be prepared from the individual reports on closed portions of meeting prepared under paragraph (c) of this section.

[44 FR 22351, Apr. 13, 1979, as amended at 45 FR 85725, Dec. 30, 1980]

§ 14.61 Transcripts of advisory committee meetings.

(a) The agency will arrange for a transcript or recording to be made for each portion of a meeting.

(b) A transcript or recording of an open portion of a meeting made by FDA is to be included in the record of the committee proceedings.

(c) A transcript or recording of any closed portion of a meeting made by FDA will not be included in the administrative record of the committee proceedings. The transcript or recording will be retained as confidential by FDA, and will not be discarded or erased.

(d) Any transcript or recording of a meeting or portion thereof which is publicly available under this section will be available at actual cost of duplication, which will be, where applicable, the fees established in § 20.42. FDA may furnish the requested transcript or recording for copying to a private contractor who shall charge directly for the cost of copying under § 20.51.

(e) A person attending any open portion of a meeting may, consistent with the orderly conduct of the meeting, record or otherwise take a transcript of the meeting. This transcription will not be part of the administrative record.

(f) Only FDA may make a transcript or recording of a closed portion of a meeting.

§ 14.65 Public inquiries and requests for advisory committee records.

(a) Public inquiries on general committee matters, except requests for records, are to be directed to: Committee Management Officer (HFA-306), Office of Management and Operations, Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

(b) Public inquiries on matters relating to a specific committee, except requests for records, are to be directed to the executive secretary or the designated agency employee listed in the FEDERAL REGISTER notices published under § 14.20.

(c) Requests for public advisory committee records, including minutes, are to be made, to FDA's Freedom of Information Staff (HFI-35) under § 20.40 and the related provisions of Part 20.

[44 FR 22351, Apr. 13, 1979, as amended at 46 FR 8456, Jan. 27, 1981]

§ 14.70 Administrative record of a public hearing before an advisory committee.

(a) Advice or recommendations of an advisory committee may be given only on matters covered in the administrative record of the committee's proceedings. Except as specified in other FDA regulations, the administrative record consists of all the following items relating to the matter:

(1) Any transcript or recording of an open portion of a meeting.

(2) The minutes of all portions of all meetings, after any deletions under § 14.60(b)(4).

(3) All written submissions to and information considered by the committee.

(4) All reports made by the committee.

(5) Any reports prepared by a consultant under § 14.31(e).

(b) The record of the proceeding is closed at the time the advisory committee renders its advice or recommendations or at any earlier time specified by the committee or in other sections in this chapter.

§ 14.75 Examination of administrative record and other advisory committee records.

(a) The administrative record and other committee records are available for public disclosure under Part 20, except as provided in paragraph (b) of this section, at the following times:

(1) The written information for consideration by the committee at any meeting: at the same time it is made available to the committee.

(2) The transcript or recording of any open portion of a meeting: as soon as it is available.

(3) The minutes of any open portion of a meeting: after they have been approved by the committee and certified by the chairman.

(4) The brief summary of any closed portion of a meeting prepared under § 14.60(c): as soon as it is available.

(5) All written information or views submitted to the committee at an open portion of a meeting: as soon as they are submitted.

(6) The minutes or portions thereof of a closed portion of a meeting—

(i) For a matter not directed to be maintained as confidential under § 14.22(i)(2): After they have been approved by the committee and certified by the chairman; and

(ii) For a matter directed to be maintained as confidential under § 14.22(i)(2): After the advice or report of the committee relevant to those minutes or portions thereof is acted upon by the Commissioner, or upon a determination by the Commissioner that such minutes or portions thereof may be made available for public disclosure without undue interference with agency or advisory committee operations.

(7) Formal advice or a report of the committee: After it has been acted upon, i.e., approved, disapproved, or rejected as inadequate, by the Commissioner, or upon a determination by the Commissioner that such formal advice or report may be made available for public disclosure without undue interference with agency or committee operations. Such formal advice or report may be retained as confidential while it is under active advisement.

(8) Any other committee records relating to the matter, except transcripts and recordings of closed portions of meetings: After the advice or report of the committee relevant to those records is acted upon by the Commissioner, or upon a determination by the Commissioner that the records may be made available for public disclosure without undue interference with agency or committee operations.

(b) The following information contained in the administrative record is not available for public examination or copying except as provided in § 12.32(g):

(1) Material provided to the committee by FDA that is exempt from public disclosure under Part 20 and the regulations referenced there.

(2) Material provided to the advisory committee by a person making a presentation described in § 14.25(c) and which is prohibited from public disclosure under Part 20 and the regulations referenced there.

(c) The Dockets Management Branch (HFA-305) will maintain a file for each committee containing the following principal records for ready access by the public:

(1) The committee charter.

(2) A list of committee members and their curricula vitae.

(3) The minutes of committee meetings.

(4) Any formal advice or report of the committee.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

Subpart E—Members of Advisory Committees

§ 14.80 Qualifications for members of standing policy and technical advisory committees.

(a) Members of a policy advisory committee—

(1) Shall have diverse interests, education, training, and experience; specific technical expertise is not a requirement;

(2) Are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service (the Commissioner has determined that, because members representing particular interests, e.g., a representative of labor, industry, consumers, or agriculture, are included on advisory committees specifically for the purpose of representing these interests, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services which the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services); and

(3) Shall be voting members.

(b) Technical advisory committee.

(1) Voting members of technical advisory committees—

(i) Shall have expertise in the subject matter with which the committee is concerned and have diverse professional education, training, and experience so that the committee will reflect a balanced composition of sufficient scientific expertise to handle the problems that come before it; and

(ii) Except for members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), are subject to the conflict of interest laws and regulations either as special Government employees or as members of the uniformed services, including the Commissioned Corps of the Public Health Service.

(2) The Commissioner shall, when required by statute, and may when not required by statute, provide for nonvoting members of a technical advisory committee to serve as representatives of and liaison with interested organizations. Nonvoting members—

(i) Shall be selected by the interested organizations, as provided in § 14.84; technical expertise in the subject matter with which the committee is involved is not a requirement; and

(ii) May be special Government employees subject to the conflict of interest laws and regulations, except as provided in § 14.84(e).

(c) A person may serve as a voting or nonvoting member on only one FDA advisory committee unless the Commissioner determines in writing that dual membership will aid the work of the committees involved and is in the public interest.

(d) Members of FDA advisory committees, and the chairman, are appointed from among those nominated under §§ 14.82 and 14.84 and from any other sources by the Secretary, or, by delegation of authority, by the Assistant Secretary for Health, or the Commissioner.

(e) Members appointed to an advisory committee serve for the duration of the committee, or until their terms of appointment expire, they resign, or they are removed from membership by the Commissioner.

(f) A committee member may be removed from membership for good cause. Good cause includes excessive absenteeism from committee meetings, a demonstrated bias that interferes with the ability to render objective advice, failure to abide by the procedures established in this subpart, or violation of other applicable rules and regulations, e.g., for nonvoting members, the provisions of § 14.86(c).

(g) Consultants appointed under § 14.31(e) are not members of advisory committees.

[44 FR 22351, Apr. 13, 1979, as amended at 53 FR 50949, Dec. 19, 1988; 54 FR 9035, Mar. 3, 1989]

§ 14.82 Nominations of voting members of standing advisory committees.

(a) The Commissioner will publish one or more notices in the FEDERAL REGISTER each year requesting nominations for voting members of all existing standing advisory committees. The notice will invite the submission of nominations for voting members from both individuals and organizations.

(b) The notice announcing the establishment of a new committee under § 14.40(b) will invite the submission of nominations for voting members.

(c) A person may nominate one or more qualified persons to an advisory committee. Nominations will specify the advisory committee for which the nominee is recommended and will include a complete curriculum vitae of the nominee. Nominations are to state that the nominee is aware of the nomination, is willing to serve as a member of the advisory committee, and appears to have no conflict of interest that would preclude membership.

(d) Voting members serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

§ 14.84 Nominations and selection of nonvoting members of standing technical advisory committees.

(a) This section applies when the Commissioner concludes that a technical advisory committee should include nonvoting members to represent and serve as a liaison with interested individuals and organizations.

(b) Except when the Commissioner concludes otherwise, nonvoting members of a technical advisory committee are selected in accordance with paragraphs (c) and (d) of this section and are normally limited to one person selected by consumer groups and organizations and one person selected by industry groups and organizations.

(c) To select a nonvoting member to represent consumer interests, except as provided in paragraph (c)(5) of this section, the Commissioner publishes a notice in the FEDERAL REGISTER requesting nominations for each specific committee, or subcommittee, for which nonvoting members are to be appointed.

(1) A period of 30 days will be permitted for submission of nominations for that committee or subcommittee. Interested persons may nominate one or more qualified persons to represent consumer interests. Although nominations from individuals will be accepted, individuals are encouraged to submit their nominations through consumer organizations as defined in paragraph (c)(3) of this section. Nominations of qualified persons for general consideration as nonvoting members of unspecified advisory committees or subcommittees may be made at any time. All nominations are to be submitted in writing to the Office of Consumer Affairs (HFE-40), Food and Drug Administration, Rm. 16-85, 5600 Fishers Lane, Rockville, MD 20857.

(2) A complete curriculum vitae of any nominee is to be included. Nominations must state that the nominee is aware of the nomination, is willing to serve as a member of an advisory committee, and appears to have no conflict of interest. The nomination must state whether a nominee is interested only in a particular advisory committee or subcommittee, or whether the nominee is interested in becoming a member of any advisory committee or subcommittee. Nominations that do not comply with the requirements of this paragraph will not be considered.

(3) The Office of Consumer Affairs will compile a list of organizations whose objectives are to promote, encourage, and contribute to the advancement of consumer education and to the resolution of consumer problems. All organizations listed are entitled to vote upon the nominees. The list will include organizations representing the public interest, consumer advocacy groups, and consumer/health branches of Federal, State, and local governments. Any organization that meets the criteria may be included on such list on request.

(4) The executive secretary, or other designated agency employee, will review the list of nominees and select three to five qualified nominees to be placed on a ballot. Names not selected will remain on a list of eligible nominees and be reviewed periodically by the Office of Consumer Affairs to determine continued interest. Upon selection of the nominees to be placed on the ballot, the curriculum vitae for each of the nominees will be sent to each of the organizations on the list

compiled under paragraph (c)(3) of this section, together with a ballot to be filled out and returned within 30 days. After the time for return of the ballots has expired, the ballots will be counted and the nominee who has received the highest number of votes will be selected as the nonvoting member representing consumer interests for that particular advisory committee or subcommittee. In the event of a tie, the Commissioner will select the winner by lot from among those tied for the highest number of votes.

(5) If a member representing consumer interests resigns or is removed before termination of the committee on which the member is serving, the following procedures will be used to appoint a replacement to serve out the term of the former member:

(i) The Commissioner will appoint the runner-up, in order of number of ballots received, on the original ballot submitted under paragraph (c)(4) of this section to fill the vacancy. If the runner-up is no longer willing to serve as a member, then the next runner up will be appointed.

(ii) If none of the nominees on the original ballot is willing to serve, or if there was only one nominee on the original ballot, the Office of Consumer Affairs will contact by telephone eligible individuals whose names have been submitted in the past as candidates for membership as representatives of consumer interests. A list of persons who are interested in serving on an advisory committee will then be prepared. The curricula vitae of these persons, together with a ballot, will be sent to a representative number of consumer organizations that have been determined to be eligible to vote for consumer representatives in accordance with paragraph (c)(3) of this section. After 4 days have elapsed, the Office of Consumer Affairs will contact the consumer organizations by telephone and elicit their votes. The candidate who has received the highest number of votes will be selected. In the event of a tie, the Commissioner will select the winner by lot from among those tied for the highest number of votes.

(d) To select a nonvoting member to represent industry interests, the Commissioner will publish, for each committee for which the Commissioner has determined to appoint a nonvoting member, a notice requesting that, within 30 days, any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests send a letter stating that interest to the FDA employee designated in the notice. After 30 days, a letter will be sent to each organization that has expressed an interest, attaching a complete list of all such organizations, and stating that it is their responsibility to consult with each other in selecting, within 60 days after receipt of the letter, a single nonvoting member to represent industry interests for that committee. If no individual is selected within 60 days, the Commissioner will select the nonvoting member representing industry interests.

(e) The Commissioner has determined that, because nonvoting members representing consumer and industry interests are included on advisory committees specifically for the purpose of representing such interests and have no vote, any financial interest covered by 18 U.S.C. 208(a) in the class which the member represents is irrelevant to the services the Government expects from them and thus is hereby exempted under 18 U.S.C. 208(b) as too remote and inconsequential to affect the integrity of their services.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9035, Mar. 3, 1989]

§ 14.86 Rights and responsibilities of nonvoting members of advisory committees.

(a) A nonvoting member of an advisory committee selected to represent and serve as a liaison with interested individuals, associations, and organizations has the same rights as any other committee member except that—

(1) A nonvoting member may vote only on procedural matters such as additional rules adopted under § 14.39(a), approval of minutes under § 14.60(a), decisions on transcripts under § 14.61(b), and future meeting dates;

(2) A nonvoting member who is a representative of industry interest may have access to data and informa-

tion that constitute a trade secret or confidential commercial or financial information as defined in § 20.61 only if the person has been appointed as a special Government employee under § 14.80(b).

(b) A nonvoting member of an advisory committee is subject to, and shall abide by, all rules and regulations adopted by FDA and the committee.

(c) It is the responsibility of the nonvoting consumer and industry members of an advisory committee to represent the consumer and industry interests in all deliberations.

(1) A nonvoting member does not represent any particular organization or group, but rather represents all interested persons within the class which the member is selected to represent. Accordingly, an interested person within the class represented by that nonvoting member may, upon request, have access to all written statements or oral briefings concerning the committee prepared by the nonvoting member for distribution to any person outside the committee. When documents are prepared with non-Government funds, persons desiring copies may be required to pay a reasonable fee to cover printing and similar costs.

(2) The nonvoting member reviews all official committee minutes to assure their completeness and accuracy.

(3) The nonvoting member acts as a liaison between the committee and the interested persons whom that member represents, and transmits requests for information from the committee and relevant information and views to the committee. The nonvoting member takes the initiative in contacting interested persons whom the member represents to seek out relevant information and views and to relate the progress of the advisory committee.

(4) A nonvoting industry member represents all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the committee that directly or indirectly affects the company employing the nonvoting industry member, the member shall so inform the committee but need not be absent during the discussion or decline to participate in the discussion. a nonvoting industry member may not discuss the company's position as such, but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company will occur in open session, except as provided in § 14.25(c).

(5) A nonvoting member of an advisory committee may not make any presentation to that advisory committee during a hearing conducted by that committee.

(6) Although a nonvoting member serves in a representative capacity, the nonvoting member shall exercise restraint in performing such functions and may not engage in unseemly advocacy or attempt to exert undue influence over the other members of the committee.

(d) A nonvoting member of an advisory committee may be removed by the Commissioner for failure to comply with this section as well as § 14.80(f).

§ 14.90 Ad hoc advisory committee members.

In selecting members of an ad hoc advisory committee, the Commissioner may use the procedures in §§ 14.82 and 14.84 or any other procedure deemed appropriate.

§ 14.95 Compensation of advisory committee members.

(a) (1) Except as provided in paragraphs (a) (2) and (3) of this section, all voting advisory committee members shall, and nonvoting members may, be appointed as special Government employees and receive a consultant fee and be reimbursed for travel expenses, including per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(2) Members of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) are not appointed as special Government employees. Any member of TEPRSSC who is not a Federal employee or member of the uniformed services, including the Commissioned Corps of the Public Health Service, shall receive a consultant fee and be reimbursed for travel expenses, including

per diem in lieu of subsistence, unless such compensation and reimbursement are waived.

(3) Voting and nonvoting advisory committee members who are members of the uniformed services, including the Commissioned Corps of the Public Health Service, provide service on Food and Drug Administration advisory committees as part of their assigned functions, are not appointed as special government employees, but are reimbursed by the Food and Drug Administration for travel expenses.

(b) Notwithstanding the member's primary residence, an advisory committee member, while attending meetings of the full committee or a subcommittee, will be paid whether the meetings are held in the Washington, D.C., area or elsewhere.

(c) A committee member who participates in any agency-directed assignment will be paid at an hourly rate when doing assigned work at home, a place of business, or in an FDA facility located within the member's commuting area, and at a daily rate when required to travel outside of that commuting area to perform the assignment. A committee member will not be paid for time spent on normal preparation for a committee meeting.

(1) An agency-directed assignment is an assignment that meets the following criteria:

(i) An activity that requires undertaking a definitive study. The activity must produce a tangible end product, usually a written report. Examples are:

(*a*) An analysis of the risks and benefits of the use of a class of drugs or a report on a specific problem generated by an IND or NDA;

(*b*) The performance of similar investigations or analysis of complex industry submissions to support advisory committee deliberations other than normal meeting preparation;

(*c*) The preparation of a statistical analysis leading to an estimate of toxicologically safe dose levels; and

(*d*) The design or analysis of animal studies of toxicity, mutagenicity, teratogenicity, or carcinogenicity.

(ii) The performance of an IND or NDA review or similar review.

(2) A committee member who undertakes a special assignment, the end product of which does not represent the end product of the advisory committee, but rather of the committee member's own assignment, can be compensated. Should this preparatory work by members collectively result in an end product of the committee, this is to be considered normal meeting preparation and committee members are not to be compensated for this work.

(d) Salary while in travel status is authorized when a committee member's ordinary pursuits are interrupted for the substantial portion of an additional day beyond the day or days spent in performing those services, and as a consequence the committee member loses some regular compensation. This applies on weekends and holidays if the special Government employee loses income that would otherwise be earned on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveler will be paid at a daily rate.

[44 FR 22351, Apr. 13, 1979, as amended at 53 FR 50949, Dec. 19, 1988]

Subpart F—Standing Advisory Committees

§ 14.100 List of standing advisory committees.

Standing advisory committees and the dates of their establishment are as follows:

(a) *Office of the Commissioner—Board of Tea Experts.*

(1) Date established: March 2, 1897.

(2) Function: Advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea imported into the United States under 21 U.S.C. 42.

(b) *Center for Biologics Evaluation and Research—*

(1) *Allergenic Products Advisory Committee.*

(i) Date established: July 9, 1984.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

(2) *Biological Response Modifiers Advisory Committee.*

(i) Date established: October 28, 1988.

(ii) Function: Reviews and evaluates data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases.The committee will also consider the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and advise the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Commissioner of Food and Drugs of its findings.

(3) *Blood Products Advisory Committee.*

(i) Date established: May 13, 1980.

(ii) Function: Reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

(4) [Reserved]

(5) *Vaccines and Related Biological Products Advisory Committee.*

(i) Date established: December 31, 1979.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

(c) *Center for Drug Evaluation and Research*—(1) *Anesthetic and Life Support Drugs Advisory Committee.*

(i) Date established: May 1, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the field of anethesiology and surgery.

(2) *Anti-Infective Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in infectious diseases.

(3) *Antiviral Drugs Advisory Committee.*

(i) *Date established:* February 15, 1989.

(ii) *Function:* Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome (AIDS), AIDS-related complex (ARC), and other viral, fungal, and mycobacterial infections.

(4) *Arthritis Advisory Committee.*

(i) Date established: April 5, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

(5) *Cardiovascular and Renal Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

(6) *Dermatologic Drugs Advisory Committee.*

(i) Date established: October 7, 1980.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of dermatologic diseases.

(7) *Drug Abuse Advisory Committee.*

(i) Date established: May 31, 1978.

(ii) Function: Advises on the scientific and medical evaluation of information gathered by the Department of Health and Human Services and the Department of Justice on the safety, efficacy, and abuse potential of drugs and recommends actions to be taken on the marketing, investigation, and control of such drugs.

(8) *Endocrinologic and Metabolic Drugs Advisory Committee.*

(i) Date established: August 27, 1970.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

(9) *Fertility and Maternal Health Drugs Advisory Committee.*

(i) Date established: March 23, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics and gynecology.

(10) *Gastrointestinal Drugs Advisory Committee.*

(i) Date established: March 3, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in gastrointestinal diseases.

(11) *Oncologic Drugs Advisory Committee.*

(i) Date established: September 21, 1978.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in treatment of cancer.

(12) *Peripheral and Central Nervous System Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in neurological disease.

(13) *Psychopharmacologic Drugs Advisory Committee.*

(i) Date established: June 4, 1974.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

(14) *Pulmonary-Allergy Drugs Advisory Committee.*

(i) Date established: February 17, 1972.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

(15) *Radiopharmaceutical Drugs Advisory Committee.*

(i) Date established: August 30, 1967.

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of nuclear medicine.

(d) *Center for Devices and Radiological Health*—

(1) Advisory panels and the dates of their establishments are as follows:

(i) *Anesthesiology and Respiratory Therapy Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(ii) *Circulatory System Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(iii) *Clinical Chemistry and Clinical Toxicology Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(iv) *Dental Products Panel.*

(A) Date established: March 5, 1988.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation. Reviews and evaluates data concerning the safety and effectiveness of over-the-counter (OTC) drug products for human use and makes appropriate recommendations to the Commissioner of Food and Drugs.

(v) *Ear, Nose, and Throat Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(vi) *Gastroenterology-Urology Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(vii) *General and Plastic Surgery Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(viii) *General Hospital and Personal Use Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(ix) *Hematology and Pathology Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(x) *Immunology Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(xi) *Microbiology Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(xii) *Neurological Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(xiii) *Obstetrics-Gynecology Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(xiv) *Ophthalmic Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(xv) *Orthopedic and Rehabilitation Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(xvi) *Radiologic Devices Panel.*

(A) Date established: April 14, 1984.

(B) Function: Reviews and evaluates data on the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

(2) *Device Good Manufacturing Practice Advisory Committee.*

(i) Date established: August 12, 1976.

(ii) Function: Reviews proposed regulations for good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of devices, and makes recommendations on the feasibility and reasonableness of the proposed regulations.

(3) *Technical Electronic Product Radiation Safety Standards Committee.*

(i) Date established: October 18, 1968.

(ii) Function: Advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

(e) *National Center for Toxicological Research—Science Advisory Board.*

(1) Date established: June 2, 1973.

(2) Function: Advises on establishment and implementation of a research program that will assist the Commissioner of Food and Drugs and the Administrator, Environmental Protection Agency, in fulfilling their regulatory responsibilities.

(f) *Center for Veterinary Medicine—Veterinary Medicine Advisory Committee.*

(1) Date established: April 24, 1984.

(2) Function: Reviews and evaluates available data concerning safety and effectiveness of marketed and investigational new animal drugs, feeds, and devices for use in the treatment and prevention of animal disease and increased animal production.

[54 FR 9036, Mar. 3, 1989, as amended at 54 FR 11698, Mar. 22, 1989]

EFFECTIVE DATE NOTE: At 54 FR 11698, Mar. 22, 1989, § 14.100 was amended by adding (c)(3). Authority for the committee referred to in this material will end on February 15, 1991, unless the Secretary of Health and Human Services formally determines that renewal is in the public interest.

Subpart G—Technical Electronic Products Radiation Safety Standards Committee

§ 14.120 Establishment of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC).

The Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), consisting of 15 members, is established in accordance with the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)(1)(A)) to provide consultation before the Commissioner prescribes any performance standard for an electronic product.

§ 14.122 Functions of TEPRSSC.

(a) In performing its function of advising the Commissioner, TEPRSSC—

(1) May propose electronic product radiation safety standards to the Commissioner for consideration;

(2) Provides consultation to the Commissioner on all performance standards proposed for consideration under 42 U.S.C. 263f; and

(3) May make recommendations to the Commissioner on any other matters it deems necessary or appropriate in fulfilling the purposes of the act.

(b) Responsibility for action on performance standards under 42 U.S.C. 263f rests with the Commissioner, after receiving the advice of TEPRSSC.

§ 14.125 Procedures of TEPRSSC.

(a) When the Commissioner is considering promulgation of a performance standard for an electronic product, or an amendment of an existing standard, before issuing a proposed regulation in the FEDERAL REGISTER the Commissioner will submit to TEPRSSC the proposed standard or amendment under consideration, together with other relevant information to aid TEPRSSC in its deliberations.

(b) The agenda and other material to be considered at any meeting will be sent to members whenever possible at least 2 weeks before the meeting.

(c) Ten members constitute a quorum, provided at least three members are present from each group specified in 42 U.S.C. 263f(f)(1)(A) and in § 14.127(a), i.e., Government, industry, and the public.

(d) The chairman of TEPRSSC will ordinarily submit a report to the Commissioner of the committee's consideration of any proposed performance standard for an electronic product within 60 days after consideration. If the chairman believes that more time is needed, the chairman will inform the Director of the Center for Devices and Radiological Health in writing, in which case an additional 30 days will be allowed to make the report.

(e) Sections 14.1 through 14.7 apply to TEPRSSC, except where other provisions are specifically included in §§ 14.120 through 14.130.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 14.127 Membership of TEPRSSC.

(a) The Commissioner will appoint the members after consultation with public and private organizations concerned with the technical aspect of electronic product radiation safety. TEPRSSC consists of 15 members, each of whom is technically qualified by training and experienced in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(1) Five members selected from government agencies, including State and Federal Governments.

(2) Five members selected from the affected industries after consultation with industry representatives.

(3) Five members selected from the general public, of whom at least one shall be a representative of organized labor.

(b) The Commissioner will appoint a committee member as chairman of TEPRSSC.

(c) Appointments of members are for a term of 3 years or as specified by the Commissioner.

(1) The chairman is appointed for a term concurrent with the chairman's term as a member of TEPRSSC. If the chairmanship becomes vacant without adequate notice, the executive secretary may appoint a committee member as temporary chairman pending appointment of a new chairman by the Commissioner.

(2) Members may not be reappointed for a second consecutive full term.

(d) A person otherwise qualified for membership is not eligible for selection as a member of TEPRSSC from Government agencies or the general public if the Commissioner determines that the person does not meet the requirements of the conflict of interest laws and regulations.

(e) Retention of membership is conditioned upon the following:

(1) Continued status as a member of the group from which the member was

selected as specified in paragraph (a) of this section.

(2) Absence of any conflict of interest during the term of membership as specified in paragraph (d) of this section.

(3) Active participation in TEPRSSC activities.

(f) Appointment as a member of TEPRSSC is conditioned on certification that the prospective member:

(1) Agrees to the procedures and criteria specified in this subpart.

(2) Has no conflict of interest as specified in paragraph (d) of this section.

(3) Will notify the executive secretary of TEPRSSC before any change in representative status on TEPRSSC which may be contrary to the conditions of the appointment.

(g) Members of TEPRSSC who are not full-time officers or employees of the United States receive compensation under § 14.95, in accordance with 42 U.S.C. 210(c).

§ 14.130 Conduct of TEPRSSC meeting; availability of TEPRSSC records.

(a) In accordance with 42 U.S.C. 263f(f)(1)(B), all proceedings of TEPRSSC are recorded, and the record of each proceeding is available for public inspection.

(b) All proceedings of TEPRSSC are open except when the Commissioner has determined, under § 14.27, that a portion of a meeting may be closed.

Subpart H—Color Additive Advisory Committees

§ 14.140 Establishment of a color additive advisory committee.

The Commissioner will establish a color additive advisory committee under the following circumstances:

(a) The Commissioner concludes, as a matter of discretion, that it would be in the public interest for a color additive advisory committee to review and make recommendations about the safety of a color additive on which important issues are pending before FDA and for interested persons to present information and views at an oral public hearing before a color additive advisory committee.

(b) There is an issue arising under section 706(b)(5)(B) of the act concerning the safety of a color additive, including its potential or actual carcinogenicity, that requires the exercise of scientific judgment and a person who would be adversely affected by the issuance, amendment, or repeal of a regulation listing a color additive requests that the matter, or the Commissioner as a matter of discretion determines that the matter should, be referred to a color additive advisory committee.

(1) Paragraph (b) does not apply to any issue arising under the transitional provisions in section 203 of the Color Additive Amendments of 1960 relating to provisional listing of commercially established colors. A color additive advisory committee to consider any such matter will be established under paragraph (a) of this section.

(2) A request for establishment of a color additive advisory committee is to be made in accordance with § 10.30. The Commissioner may deny any petition if inadequate grounds are stated for establishing a color additive advisory committee. A request for establishment of a color additive advisory committee may not rest on mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires scientific judgment and justifies a hearing before a color additive advisory committee. When it conclusively appears from the request for a color additive advisory committee that the matter is premature or that it does not involve an issue arising under section 706(b)(5)(B) of the act or that there is no genuine and substantial issue of fact requiring scientific judgment, or for any other reason a color additive advisory committee is not justified, the Commissioner may deny the establishment of a color additive advisory committee.

(3) Establishment of a color additive advisory committee on the request of an interested person is conditioned upon receipt of the application fee specified in § 14.155.

(4) Any person adversely affected may request referral of the matter to a color additive advisory committee at any time before, or within 30 days

after, publication of an order of the Commissioner acting upon a color additive petition or proposal.

§ 14.142 Functions of a color additive advisory committee.

(a) A color additive advisory committee reviews all available information relating to the matter referred to it, including all information contained in any pertinent color additive petition and in FDA files. All information reviewed is placed on public display and is available for review at the office of the Dockets Management Branch.

(b) The Commissioner specifies to the color additive advisory committee, in writing, the issues on which review and recommendations are requested.

(c) The date of the first meeting of a color additive advisory committee, following receipt of the administrative record by each of the committee members, is designated as the beginning of the period allowed for consideration of the matter by the committee. Within 60 days after the first meeting, unless the time is extended as provided in paragraph (d) of this section, the chairman of the committee shall certify to the Commissioner the report containing the recommendations of the committee, including any minority report. The report states the recommendations of the committee and the reasons or basis for them. The report includes copies of all material considered by the committee in addition to the administrative record furnished to it.

(d) If the chairman concludes that the color additive advisory committee needs additional time, the chairman shall so inform the Commissioner in writing and may certify the report of the committee to the Commissioner within 90 days instead of 60 days.

(e) More than one matter may be handled concurrently by a color additive advisory committee.

§ 14.145 Procedures of a color additive advisory committee.

(a) A color additive advisory committee is subject to all the requirements of the Federal Advisory Committee Act and this part.

(b) All interested persons have a right to consult with the color additive advisory committee reviewing a matter and to submit information and views to a color additive advisory committee, in accordance with the procedures in this part.

§ 14.147 Membership of a color additive advisory committee.

(a) The members of a color additive advisory committee are selected in the following manner:

(1) If a color additive advisory committee is established for purposes that do not include review of an issue arising under section 706(b)(5)(B) of the act, or is established on the initiative of the Commissioner, the Commissioner may use the procedure in paragraph (a)(2) of this section to select the members or may use an existing standing advisory committee listed in § 14.100, or may establish a new advisory committee under this subpart. Once the Commissioner has established a color additive advisory committee under this paragraph and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations about that color additive.

(2) If the Commissioner established a color additive advisory committee to review an issue arising under section 706(b)(5)(B) of the act on the request of an interested person, it shall be established under the following requirements:

(i) Except as provided in paragraph (a)(2) (ii) and (iii) of this section, the Commissioner will request the National Academy of Sciences to select the members of a color additive advisory committee from among experts qualified in the subject matter to be reviewed by the committee, and of adequately diversified professional backgrounds. The Commissioner will appoint one of the members as the chairman.

(ii) If the National Academy of Sciences is unable or refuses to select the members of a color additive advisory committee, the Commissioner will select the members.

(iii) If the Commissioner and the requesting party agree, section 706(b)(5)(D) of the act may be waived and the matter may be referred to any standing advisory committee listed in § 14.100 or to any advisory committee established under any other procedure that is mutually agreeable. Once the Commissioner has established a color additive advisory committee and has referred to it a matter relating to a color additive, no interested person may subsequently request that an additional or different color additive advisory committee be established to review and make recommendations about that color additive.

(b) Members of a color additive advisory committee are subject to the requirements of the Federal Advisory Committee Act and this subpart, except that no member of a color additive advisory committee may by reason of such membership alone be a special government employee or be subject to the conflict of interest laws and regulations.

§ 14.155 Fees and compensation pertaining to a color additive advisory committee.

(a) When a matter is referred to a color additive advisory committee, all related costs, including personal compensation of committee members, travel, materials, and other costs, are borne by the person requesting the referral, such costs to be assessed on the basis of actual cost to the government. The compensation of such costs includes personal compensation of committee members at a rate not to exceed $128.80 per member per day.

(b) In the case of a request for referral to a color additive advisory committee, a special advance deposit is to be made in the amount of $2,500. Where required, further advances in increments of $2,500 each are to be made upon request of the Commissioner. All deposits for referrals to a color additive advisory committee in excess of actual expenses will be refunded to the depositor.

(c) All deposits and fees required by this section are to be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectable at par in Washington, DC. All deposits and fees are to be forwarded to the Associate Commissioner for Management and Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, and after appropriate record of them is made, they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(d) The Commissioner may waive or refund such fees in whole or in part when, in the Commissioner's judgment, such action will promote the public interest. Any person who believes that payment of these fees will be a hardship may petition the Commissioner under § 10.30 to waive or refund the fees.

Subpart I—Advisory Committees for Human Prescription Drugs

§ 14.160 Establishment of standing technical advisory committees for human prescription drugs.

The standing technical advisory committees for human prescription drugs are established to advise the Commissioner:

(a) Generally on the safety and effectiveness, including the labeling and advertising, and regulatory control of the human prescription drugs falling within the pharmacologic class covered by the advisory committee and on the scientific standards appropriate for a determination of safety and effectiveness in that class of drugs.

(b) Specifically on any particular matter involving a human prescription drug pending before FDA, including whether the available information is adequate to support a determination that—

(1) A particular IND study may properly be conducted;

(2) A particular drug meets the statutory standard for proof of safety and effectiveness necessary for approval or continued approval for marketing; or

(3) A particular drug is properly classified as a new drug, an old drug, or a banned drug.

§ 14.171 Utilization of an advisory committee on the initiative of FDA.

(a) Any matter involving a human prescription drug under review within the agency may, in the discretion of the Commissioner, be the subject of a public hearing and continuing or periodic review by the appropriate standing technical advisory committee for human prescription drugs. The Commissioner's determinations on the agenda of the committee are based upon the priorities of the various matters pending before the agency which fall within the pharmacologic class covered by that committee.

(b) High priority for such hearing and review by the appropriate standing technical advisory committee for human prescription drugs are given to the following types of human prescription drugs:

(1) Investigational drugs which are potential therapeutic advances over currently marketed products from the standpoint of safety or effectiveness, or which pose significant safety hazards, or which present narrow benefit-risk considerations requiring a close judgmental decision on approval for marketing, or which have a novel delivery system or formulation, or which are the subject of major scientific or public controversy, or which may be subject to special regulatory requirements such as a limitation on clinical trials, a patient followup requirement, postmarketing Phase IV studies, distributional controls, or boxed warnings.

(2) Marketed drugs for which an important new use has been discovered or which pose newly discovered safety hazards, or which are the subject of major scientific or public controversy, or which may be subject to important regulatory actions such as withdrawal of approval for marketing, boxed warnings, distributional controls, or newly required scientific studies.

(c) The committee may request the Commissioner for an opportunity to hold a public hearing and to review any matter involving a human prescription drug which falls within the pharmacologic class covered by the committee. The Commissioner may, after consulting with the committtee on such request, grant or deny the request in light of the priorities of the other matters pending before the committee. Whenever feasible, consistent with the other work of the committee, the request will be granted.

(d) For a drug that meets any of the criteria established in paragraph (b) of this section, one or more members of or consultants to the appropriate advisory committee may be selected for more detailed monitoring of the matter and consultation with FDA on behalf of the committee. The member or consultant may be invited to attend appropriate meetings and shall assist the center in any briefing of the committee on that matter.

(e) An advisory committee may obtain advice and recommendations from other agency advisory committees, consultants, and experts which the advisory committee and the center conclude would facilitate the work of the advisory committee.

(f) Presentation of all relevant information about the matter will be made in open session unless it relates to an IND the existence of which has not previously been disclosed to the public as defined in § 20.81 or is otherwise prohibited from public disclosure under part 20 and the regulations referenced therein. Sections 314.430 and 601.51 determine whether, and the extent to which, relevant information may be made available for public disclosure, summarized and discussed in open session but not otherwise made available for public disclosure, or not in any way discussed or disclosed in open session or otherwise disclosed to the public.

[44 FR 22351, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 14.172 Utilization of an advisory committee at the request of an interested person.

Any interested person may request, under § 10.30, that a specific matter relating to a particular human prescription drug be submitted to an appropriate advisory committee for a hearing and review and recommendations. The request must demonstrate the importance of the matter and the reasons why it should be submitted for a hearing at that time. The Commissioner may grant or deny the request.

§ 14.174 Advice and recommendations in writing.

Advice and recommendations given by a committee on a specific drug or a class of drugs are ordinarily in the form of a written report. The report may consist of the approved minutes of the meeting or a separate written report. The report responds to the specific issues or questions which the Commissioner has addressed to the advisory committee, and states the basis of the advice and recommendations of the committee.

PART 15—PUBLIC HEARING BEFORE THE COMMISSIONER

Subpart A—General Provisions

Sec.
15.1 Scope.

Subpart B—Procedures for Public Hearing Before the Commissioner

15.20 Notice of a public hearing before the Commissioner.
15.21 Notice of participation; schedule for hearing.
15.25 Written submissions.
15.30 Conduct of a public hearing before the Commissioner.

Subpart C—Records of a Public Hearing Before the Commissioner

15.40 Administrative record.
15.45 Examination of administrative record.

AUTHORITY: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.): sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1—9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1—10, Chap. 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.).

SOURCE: 44 FR 22366, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 15.1 Scope.

The procedures in this part apply when:

(a) The Commissioner concludes, as a matter of discretion, that it is in the public interest to permit persons to present information and views at a public hearing on any matter pending before the Food and Drug Administation.

(b) The act or regulation specifically provides for a public hearing before the Commissioner on a matter, e.g., § 330.10(a)(8) relating to over-the-counter drugs and sections 520 (b) and (f)(1)(B), and 521 of the act relating to proposals to allow persons to order custom devices, to proposed device good manufacturing practice regulations, and to proposed exemptions from preemption of State and local device requirements under § 808.25(e).

(c) A person who has right to an opportunity for a formal evidentiary public hearing under Part 12 waives that opportunity and instead requests under § 12.32 a public hearing before the Commissioner, and the Commissioner, as a matter of discretion, accepts the request.

Subpart B—Procedures for Public Hearing Before the Commissioner

§ 15.20 Notice of a public hearing before the Commissioner.

(a) If the Commissioner determines that a public hearing should be held on a matter, the Commissioner will publish a notice of hearing in the FEDERAL REGISTER setting forth the following information:

(1) If the hearing is under § 15.1 (a) or (b), the notice will state the following:

(i) The purpose of the hearing and the subject matter to be considered. If a written document is to be the subject matter of the hearing, it will be published as part of the notice, or reference made to it if it has already been published in the FEDERAL REGISTER, or the notice will state that the document is available from an agency office identified in the notice.

(ii) The time, date, and place of the hearing, or a statement that the information will be contained in a subsequent notice.

(2) If the hearing is in lieu of a formal evidentiary public hearing under § 15.1(c), all of the information described in § 12.32(e).

(b) The scope of the hearing is determined by the notice of hearing and any regulation under which the hearing is held. If a regulation, e.g., § 330.10(a)(10), limits a hearing to review of an existing administrative record, information not already in the record may not be considered at the hearing.

(c) The notice of hearing may require participants to submit the text of their presentations in advance of the hearing if the Commissioner determines that advance submissions are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e). The notice may provide for the submission of a comprehensive outline as an alternative to the submission of the text if the Commissioner determines that submission of an outline will be sufficient.

(Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1—9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1—10, Chap. 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.); the Agriculture, Rural Development, and Related Agencies Bill (Pub. L. 95-448, 92 Stat. 1073, 1091); and 21 CFR 5.1)

[44 FR 22366, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982]

§ 15.21 Notice of participation; schedule for hearing.

(a) The notice of hearing will provide persons an opportunity to file a written notice of participation with the Dockets Management Branch within a specified period of time containing the information specified in the notice, e.g., name of participant, address, phone number, affiliation, if any, topic of presentation and approximate amount of time requested for the presentation. If the public interest requires, e.g., a hearing is to be conducted within a short period of time or is to be primarily attended by individuals without an organizational affiliation, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given or provide for submitting notices of participation at the time of the hearing. A written or oral notice of participation must be received by the designated person by the close of business of the day specified in the notice.

(b) Promptly after expiration of the time for filing a notice, the Commissioner will determine the amount of time allotted to each person and the approximate time that oral presentation is scheduled to begin. If more than one hearing is held on the same subject, a person will ordinarily be allotted time for a presentation at only one hearing.

(c) Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and to request time for a joint presentation. The Commissioner may require joint presentations by persons with common interests.

(d) The Commissioner will prepare a hearing schedule showing the persons making oral presentations and the time alloted to each person, which will be filed with the Dockets Management Branch and mailed or telephoned before the hearing to each participant.

(e) The hearing schedule will state whether participants must be present by a specified time to be sure to be heard in case the absence of participants advances the schedule.

§ 15.25 Written submissions.

A person may submit information or views on the subject of the hearing in writing to the Dockets Management Branch, under § 10.20. The record of the hearing will remain open for 15 days after the hearing is held for any additional written submissions, unless the notice of the hearing specifies otherwise or the presiding officer rules otherwise.

§ 15.30 Conduct of a public hearing before the Commissioner.

(a) The Commissioner or a designee may preside at the hearing, except where a regulation provides that the Commissioner will preside personally. The presiding officer may be accompanied by other FDA employees or other Federal Government employees designated by the Commissioner, who may serve as a panel in conducting the hearing.

(b) The hearing will be transcribed.

(c) Persons may use their alloted time in whatever way they wish, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written information or views for inclusion in the record of the hearing, subject to the requirements of § 15.25. The presiding officer may allot additional time to any person when the officer concludes that it is in the public interest, but may not reduce the time allotted for any person without the consent of the person.

(d) If a person is not present at the time specified for the presentation, the persons following will appear in order, with adjustments for those appearing at their scheduled time. An attempt will be made to hear any person who is late at the conclusion of the hearing. Other interested persons attending the hearing who did not request an opportunity to make an oral presentation will be given an opportunity to make an oral presentation at the conclusion of the hearing, in the discretion of the presiding officer, to the extent that time permits.

(e) The presiding officer and any other persons serving on a panel may question any person during or at the conclusion of the presentation. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer or panel for response by them or by persons attending the hearing.

(f) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views may be made or considered, but other participants may comment upon or rebut all such information and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

(g) The hearing may end early only if all persons scheduled for a later presentation have already appeared or it is past the time specified in the hearing schedule, under § 15.21(e), by which participants must be present.

(h) The Commissioner or the presiding officer may, under § 10.19, suspend, modify, or waive any provision of this part.

Subpart C—Records of a Public Hearing Before the Commissioner

§ 15.40 Administrative record.

(a) The administrative record of a public hearing before the Commissioner consists of the following:

(1) All relevant FEDERAL REGISTER notices, including any documents to which they refer.

(2) All written submissions under § 15.25.

(3) The transcript of the oral hearing.

(b) The record of the administrative proceeding will be closed at the time specified in § 15.25.

§ 15.45 Examination of administrative record.

Section 10.20(j) governs the availability for public examination and copying of each document in the administrative record of the hearing

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

Subpart A—General Provisions

Sec.
16.1 Scope.
16.5 Inapplicability and limited applicability.

Sec.

Subpart B—Initiation of Proceedings

16.22 Initiation of regulatory hearing.
16.24 Regulatory hearing required by the act or a regulation.
16.26 Denial of hearing and summary decision.

Subpart C—Commissioner and Presiding Officer

16.40 Commissioner.
16.42 Presiding officer.
16.44 Communication to presiding officer and Commissioner.

Subpart D—Procedures for Regulatory Hearing

16.60 Hearing procedure.
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Subpart E—Administrative Record and Decision

16.80 Administrative record of a regulatory hearing.
16.85 Examination of administrative record.
16.95 Administrative decision and record for decision.

Subpart F—Reconsideration and Stay

16.119 Reconsideration and stay of action.

Subpart G—Judicial Review

16.120 Judicial review.

AUTHORITY: Secs. 1 et seq., 2 et seq.; 15 U.S.C. 401 et seq., 1451 et seq.; secs. 1-10, 1-9, 201 et seq., 24(b), 409(b), 100 et seq., 2 et seq.; 21 U.S.C. 41-50, 141-149, 321 et seq., 467f(b), 679(b), 821 et seq., 1031 et seq.; secs. 1 et seq., 4; 42 U.S.C. 201 et seq., 257a; 21 CFR 5.10.

SOURCE: 44 FR 22367, Apr. 13, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 16.1 Scope.

The procedures in this part apply when:

(a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.

(b) The act or a regulation provides a person with an opportunity for a hearing on a regulatory action, including proposed action, and the act or a regulation either specifically provides an opportunity for a regulatory hearing under this part or provides an opportunity for a hearing for which no procedures are specified by regulation. Listed below are the statutory and regulatory provisions under which regulatory hearings are available:

(1) Statutory provisions:

Section 304(g) of the act relating to the administrative detention of devices (see § 800.55(g)).

Section 514(g)(4)(B) of the act relating to an action to make a device performance standard effective upon publication.

Section 515(e)(1) of the act relating to the proposed withdrawal of approval of a device premarket approval application.

Section 515(f)(6) of the act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.

Section 515(f)(7) of the act relating to revocation of a notice of completion of a product development protocol.

Section 516 of the act relating to a proposed banned device regulation (see § 895.21(d)).

Section 518(b) of the act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.

Section 520(f)(2)(D) of the act relating to exemptions or variances from device good manufacturing practice requirements (see § 820.1(d)).

Section 520(g)(4) and (5) of the act relating to disapproval and withdrawal of approval of an application for an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c)).

Section 520(1)(2) of the act relating to approval or denial of a petition to reclassify a class III device that FDA previously had regarded as a new drug (see § 860.136).

(2) Regulatory provisions:

§ 56.121(a), relating to disqualifying an institutional review board or an institution.

§ 71.37(a), relating to use of food containing a color additive.

§ 80.31(b), relating to refusal to certify a batch of a color additive.

§ 80.34(b), relating to suspension of certification service for a color additive.

§ 130.17(1), relating to a temporary permit to vary from a food standard.

§ 170.17(b), relating to use of food containing an investigational food additive.

§ 202.1(j)(5), relating to approval of prescription drug advertisements.

§ 312.70, relating to whether an investigator is entitled to receive investigational new drugs.

§ 312.70(d) and 312.44, relating to termination of an IND for a sponsor.

§ 312.160(b), relating to termination of an IND for tests in vitro and in laboratory research animals for a sponsor.

§ 429.50, relating to suspension of certification service for an insulin drug.

§ 431.52, relating to suspension of certification service for an antibiotic drug.

§ 433.2(d), relating to exemption from certification for an antibiotic drug.

§ 433.12(b)(5), relating to an exemption from labeling for a certifiable antibiotic drug.

§ 433.13(b), relating to an exemption from manufacturing use for a certifiable antibiotic drug.

§ 433.14(b), relating to an exemption for storage for a certifiable antibiotic drug.

§ 433.15(b), relating to an exemption for processing for a certifiable antibiotic drug.

§ 433.16(b), relating to an exemption for repacking for a certifiable antibiotic drug.

§ 511.1(b)(5), relating to use of food containing an investigational new animal drug.

§ 511.1(c)(1), relating to termination of an INAD for an investigator.

§ 511.1(c) (4) and (d), relating to termination of an INAD for a sponsor.

§ 514.210, relating to suspension of certification service for a veterinary antibiotic drug.

§ 814.46(c) relating to withdrawal of approval of a device premarket approval application.

§ 1003.11(a)(3), relating to the failure of an electronic product to comply with an applicable standard or to a defect in an electronic product.

§ 1003.31(d), relating to denial of an exemption from notification requirements for an electronic product which fails to comply with an applicable standard or has a defect.

§ 1004.6, relating to plan for repurchase, repair, or replacement of an electronic product.

§ 1210.30, relating to denial, suspension, or revocation of a permit under the Federal Import Milk Act.

(Secs. 301, 501, 502, 520, 701(a), 702, 704, 801, 52 Stat. 1042-1043 as amended, 1049-1051 as amended, 1055, 1056-1058 as amended, 67 Stat. 476-477 as amended, 90 Stat. 565-574, (21 U.S.C. 331, 351, 352, 360, 371(a), 372, 374, 381); secs. 201 et seq. 52 Stat. 1040-1059 as amended (21 U.S.C. 321 et seq.))

[44 FR 22367, Apr. 13, 1979, as amended at 45 FR 3750, Jan 18, 1980; 45 FR 10332, Feb. 15, 1980; 46 FR 8975, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981; 51 FR 26364, July 22, 1986; 54 FR 9037, Mar. 3, 1989]

§ 16.5 Inapplicability and limited applicability.

(a) This part does not apply to the following:

(1) Informal presentation of views before reporting a criminal violation under section 305 of the act and section 5 of the Federal Import Milk Act and § 1210.31.

(2) A hearing on a refusal of admission of a food, drug, device, or cosmetic under section 801(a) of the act and § 1.94, or of an electronic product under section 360(a) of the Public Health Service Act and § 1005.20.

(3) Factory inspections, recalls, regulatory letters, and similar compliance activities related to law enforcement.

(b) If a regulation provides a person with an opportunity for hearing and specifies some procedures for the hearing but not a comprehensive set of procedures, the procedures in this part apply to the extent that they are supplementary and not in conflict with the other procedures specified for the hearing. Thus, the procedures in Subpart A of Part 108 relating to emergency permit control are supplemented by the nonconflicting procedures in this part, e.g., the right to counsel, public notice of the hearing, reconsideration and stay, and judicial review.

Subpart B—Initiation of Proceedings

§ 16.22 Initiation of regulatory hearing.

(a) A regulatory hearing is initiated by a notice of opportunity for hearing from FDA. The notice will—

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by this part; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone number of the FDA employee to whom any request for hearing is to be addressed.

(5) Refer to FDA's guideline on electronic media coverage of its adminis-

trative proceedings (21 CFR Part 10, Subpart C).

(b) A person offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 3 working days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated FDA employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Commissioner will designate a presiding officer, and the hearing will take place at a time and location agreed upon by the party requesting the hearing, the FDA, and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

(d) A notice of opportunity for hearing under this section will not operate to delay or stay any administrative action, including enforcement action by the agency unless the Commissioner, as a matter of discretion, determines that delay or a stay is in the public interest.

(Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1—9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1—10, Chap. 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.); the Agriculture, Rural Development, and Related Agencies Bill (Pub. L. 95-448, 92 Stat. 1073, 1091); and 21 CFR 5.1)

[44 FR 22367, Apr. 13, 1979, as amended at 49 FR 32173, Aug. 13, 1984]

§ 16.24 Regulatory hearing required by the act or a regulation.

(a) A regulatory hearing required by the act or a regulation under § 16.1(b) will be initiated in the same manner as other regulatory hearings subject to the additional procedures in this section.

(b) [Reserved]

(c) The notice will state whether any action concerning the matter that is the subject of the opportunity for hearing is or is not being taken pending the hearing under paragraph (d) of this section.

(d) The Commissioner may take such action pending a hearing under this section as the Commissioner concludes is necessary to protect the public health, except where expressly prohibited by statute or regulation. A hearing to consider action already taken, and not stayed by the Commissioner, will be conducted on an expedited basis.

(e) The hearing may not be required to be held at a time less than 2 working days after receipt of the request for hearing.

(f) Before the hearing, FDA will give to the party requesting the hearing reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the decision or action taken or proposed that is the subject of the hearing and a general summary of the information that will be presented by FDA at the hearing in support of the decision or action. This information may be given orally or in writing, in the discretion of FDA.

(g) FDA and the party requesting the hearing will, if feasible, at least 1 day before the hearing provide to each other written notice of any published articles or written information to be presented at or relied on at the hearing. A copy will also be provided in advance if the other participant could not reasonably be expected to have or be able to obtain a copy. If written notice or a copy is not provided, the presiding officer may, if time permits, allow the party who did not receive the notice or copy additional time after the close of the hearing to make a submission concerning the article or information.

(Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91-513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91-513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85-172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91-597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1—9, Pub. L. 625, 44 Stat. 1101-1103 as amended (21 U.S.C. 141-149); secs. 1—10, Chap. 358, 29 Stat. 604-607 as amended (21 U.S.C. 41-50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89-755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.); the Agriculture, Rural Development, and Related Agencies Bill (Pub. L. 95-448, 92 Stat. 1073, 1091); and 21 CFR 5.1)

[44 FR 22367, Apr. 13, 1979, as amended at 47 FR 26375, June 18, 1982; 54 FR 9037, Mar. 3, 1989]

§ 16.26 Denial of hearing and summary decision.

(a) A request for a hearing may be denied, in whole or in part, if the Commissioner or the FDA official to whom the authority to make the final decision on the matter has been delegated under Part 5 determines that no genuine and substantial issue of fact has been raised by the material submitted. If the Commissioner or his or her delegate determines that a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for denial.

(b) After a hearing commences, the presiding officer may issue a summary decision on any issue in the hearing if the presiding officer determines from the material submitted in connection with the hearing, or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue. For the purpose of this paragraph, a hearing commences upon the receipt by FDA of a request for hearing submitted under § 16.22(b).

(c) The Commissioner or his or her delegate may review any summary decision of the presiding officer issued under paragraph (b) of this section at the request of a party or on the Commissioner's or his or her delegate's own initiative.

[53 FR 4615, Feb. 17, 1988]

Subpart C—Commissioner and Presiding Officer

§ 16.40 Commissioner.

Whenever the Commissioner has delegated authority under Part 5 on a matter for which a regulatory hearing is available under this part, the functions of the Commissioner under this part may be performed by any of the officials to whom the authority has been delegated, e.g., a center director.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 16.42 Presiding officer.

(a) An FDA employee to whom the Commissioner delegates such authority, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer and conduct a regulatory hearing under this part.

(b) In a regulatory hearing required by the act or a regulation, the presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Commissioner, who has participated in such investigation or action.

(c)(1) The Commissioner or the delegate under § 16.40 is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing. If there has been prior participation, the Commissioner or the delegate should, if feasible, designate a presiding officer for the hearing who is not a subordinate. Thus, if the Commissioner's authority to make a final decision has been delegated to a center director, the presiding officer may be an official in another center or the office of the Commissioner. The exercise of general supervisory responsibility, or the designation of the presiding officer, does not constitute prior participation in the investigation or action that is the subject of the hearing so as to preclude the Commissioner or delegate from designating a subordinate as the presiding officer.

(2) The party requesting a hearing may make a written request to have the Commissioner or the delegate

under § 16.40 be the presiding officer, notwithstanding paragraph (c)(1) of this section. If accepted as a matter of discretion, by the Commissioner or the delegate, the request is binding upon the party making the request.

(3) A different presiding officer may be substituted for the one originally designated under § 16.22 without notice to the parties.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

§ 16.44 Communication to presiding officer and Commissioner.

(a) Regulatory hearings are not subject to the separation of functions rules in § 10.55.

(b) Those persons who are directly involved in the investigation or presentation of the position of FDA or any party at a regulatory hearing that is required by the act or a regulation should avoid any off-the-record communication on the matter to the presiding officer or the Commissioner or their advisors if the communication is inconsistent with the requirement of § 16.95(b)(1) that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(c) A copy of any letter or memorandum of meeting between a participant in the hearing and the presiding officer or the Commissioner, e.g., a response by the presiding officer to a request for a change in the time of the hearing, is to be sent to all participants by the person writing the letter or the memorandum.

Subpart D—Procedures for Regulatory Hearing

§ 16.60 Hearing procedure.

(a) A regulatory hearing is public, except when the Commissioner determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy; to prevent the disclosure of a trade secret or confidential commercial or financial information that is not available for public disclosure under § 20.61; or to protect investigatory records complied for law enforcement purposes that are not available for public disclosure under § 20.64.

(1) The Commissioner may determine that a regulatory hearing is closed either on the Commissioner's initiative or on a request by the party asking for a regulatory hearing, in the request for the hearing.

(2) If the hearing is a private hearing, no persons other than the party requesting the hearing, counsel and witnesses, and an employee or consultant or other person subject to a commercial arrangement as defined in § 20.81(a) and FDA representatives with a direct professional interest in the subject matter of the proceeding are entitled to attend.

(3) If the hearing is a public hearing, it will be announced on the public calendar described in § 10.100(a) whenever feasible, and any interested person who attends the hearing may participate to the extent of presenting relevant information.

(b) A regulatory hearing will be conducted by a presiding officer. Employees of FDA will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The party requesting the hearing may then present any oral or written information relevant to the hearing. All parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but any other party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The party requesting the hearing may have the hearing transcribed, at the party's expense, in which case a copy of the transcript is to be furnished to

FDA. Any transcript of the hearing will be included with the presiding officer's report of the hearing.

(e) The presiding officer shall prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. Whenever time permits, the parties to the hearing will be given the opportunity to review and comment on the presiding officer's report of the hearing.

(f) The presiding officer shall include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and shall include a recommended decision, with a statement of reasons, unless the Commissioner directs otherwise.

(g) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this part concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(h) The Commissioner or the presiding officer has the power under § 10.19 to suspend, modify, or waive any provision of this part.

§ 16.62 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

Subpart E—Administrative Record and Decision

§ 16.80 Administrative record of a regulatory hearing.

(a) The administrative record of the regulatory hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's report of the hearing and comments on the report under § 16.60(e).

(5) All letters and memoranda of meetings or communications between participants and the presiding officer or the Commissioner referred to in § 16.44(c).

(b) The record of the regulatory hearing is closed to the submission of information and views, at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

§ 16.85 Examination of administrative record.

Part 20 governs the availability for public disclosure of each document that is a part of the administrative record of a regulatory hearing.

§ 16.95 Administrative decision and record for decision.

(a) With respect to a regulatory hearing at the Commissioner's initiative under § 16.1(a), the Commissioner shall consider the administrative record of the hearing specified in § 16.80(a) together with all other relevant information and views available to FDA in determining whether regulatory action should be taken and, if so, in what form.

(b) With respect to a regulatory hearing required by the act or a regulation under § 16.1(b)—

(1) The administrative record of the hearing specified in § 16.80(a) constitutes the exclusive record for decision;

(2) On the basis of the administrative record of the hearing, the Commissioner shall issue a written decision stating the reasons for the Commissioner's administrative action and the basis in the record; and

(3) For purposes of judicial review under § 10.45, the record of the administrative proceeding consists of the record of the hearing and the Commissioner's decision.

Subpart F—Reconsideration and Stay

§ 16.119 Reconsideration and stay of action.

After any final administrative action that is the subject of a hearing under this part, any party may petition the Commissioner for reconsideration of any part or all of the decision or action under § 10.33 or may petition for a stay of the decision or action under § 10.35.

[44 FR 22367, Apr. 13, 1979, as amended at 54 FR 9037, Mar. 3, 1989]

Subpart G—Judicial Review

§ 16.120 Judicial review.

Section 10.45 governs the availability of judicial review concerning any regulatory action which is the subject of a hearing under this part

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

Subpart A—General Provisions

Sec.
19.1 Scope.
19.5 Reference to Department regulations.
19.6 Code of ethics for government service.
19.10 Food and Drug Administration Conflict of Interest Review Board.

Subpart B—Reporting of Violations

19.21 Duty to report violations.

Subpart C—Disqualification Conditions

19.45 Temporary disqualification of former employees.
19.55 Permanent disqualification of former employees.

AUTHORITY: Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)); 21 CFR 5.10.

SOURCE: 42 FR 15615, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 19.1 Scope.

This part governs the standards of conduct for, and establishes regulations to prevent conflicts of interest by, all Food and Drug Administration employees.

§ 19.5 Reference to Department regulations.

(a) The provisions of 45 CFR Part 73, establishing standards of conduct for all Department employees, are fully applicable to all Food and Drug Administration employees, except that such regulations shall be applicable to special government employees, i.e., consultants to the Food and Drug Administration, only to the extent stated in Subpart L of 45 CFR Part 73.

(b) The provisions of 45 CFR Part 73a supplement the Department standards of conduct and apply only to Food and Drug Administration employees except special government employees.

§ 19.6 Code of ethics for government service.

The following code of ethics, adopted by Congress on July 11, 1958, shall apply to all Food and Drug Administration employees:

CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

1. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

2. Uphold the Constitution, laws, and legal regulations of the United States and of all governments therein and never be a party to their evasion.

3. Give a full day's labor for a full day's pay; giving to the performance of his duties his earnest effort and best thought.

4. Seek to find and employ more efficient and economical ways of getting tasks accomplished.

5. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or his family, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of his governmental duties.

6. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

7. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of his governmental duties.

8. Never use any information coming to him confidentially in the performance of governmental duties as a means for making private profit.

9. Expose corruption wherever discovered.

10. Uphold these principles, ever conscious that public office is a public trust.

§ 19.10 Food and Drug Administration Conflict of Interest Review Board.

(a) The Commissioner shall establish a permanent five-member Conflict of Interest Review Board, which shall review and make recommendations to the Commissioner on all specific or policy matters relating to conflicts of interest arising within the Food and Drug Administration that are forwarded to it by: (1) The Associate Commissioner for Management and Operations or (2) anyone who is the subject of an adverse determination by the Associate Commissioner for Management and Operations on any matter arising under the conflict of interest laws, except a determination of an apparent violation of law. The Director, Division of Human Resources Management, Office of Management and Operations, shall serve as executive secretary of the Review Board.

(b) It shall be the responsibility of every Food and Drug Administration employee with whom any specific or policy issue relating to conflicts of interest is raised, or who otherwise wishes to have any such matter resolved, to forward the matter to the Associate Commissioner for Management and Operations for resolution, except that reporting of apparent violations of law are governed by § 19.21.

(c) All general policy relating to conflicts of interest shall be established in guidelines pursuant to the provisions of § 10.90(b) of this chapter and whenever feasible shall be incorporated in regulations in this subpart.

(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Freedom of Information Staff, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

(1) A determination that an employee must dispose of prohibited financial interests or refrain from incompatible outside activities in accordance with established Department or agency regulations.

(2) A determination that a proposed consultant is not eligible for employment by the agency.

(3) A determination that public disclosure of any information would constitute an unwarranted invasion of personal privacy in violation of § 20.63 of this chapter.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

Subpart B—Reporting of Violations

§ 19.21 Duty to report violations.

(a) The Division of Ethics and Program Integrity, Office of Management and Operations, is responsible for obtaining factual information for the Food and Drug Administration on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by agency personnel.

(b) Any Food and Drug Administration employee who has factual information showing or who otherwise believes that any present or former Food and Drug Administration employee has violated or is violating any provision of this subpart or of 45 CFR Parts 73 or 73a or of any statute listed in Appendix A to 45 CFR Part 73 should report such information directly to the Division of Ethics and Program Integrity. Any such reports shall be in writing or shall with the assistance of the Division of Ethics and Program Integrity, be reduced to writing, and shall be promptly investigated.

(c) Any report pursuant to paragraph (b) of this section and any records relating to an investigation of such reports shall be maintained in strict confidence in the files of the Division of Ethics and Program Integrity, shall be exempt from public disclosure, and may be reviewed only by authorized Food and Drug Administration employees who are required to do so in the performance of their duties.

[42 FR 15615, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

Subpart C—Disqualification Conditions

§ 19.45 Temporary disqualification of former employees.

Within 1 year after termination of employment with the Food and Drug Administration, no former Food and Drug Administration employee, including a special government employee, shall appear personally before the Food and Drug Administration or other federal agency or court as agent or attorney for any person other than the United States in connection with any proceeding or matter in which the United States is a party or has a direct and substantial interest and which was under his official responsibility at any time within one year preceding termination of such responsibility. The term "official responsibility" means the direct administrative or operating authority, whether intermediate or final, and either exercisable alone or with others, and either personally or through subordinates, to approve, disapprove, or otherwise direct government action.

§ 19.55 Permanent disqualification of former employees.

No former Food and Drug Administration employee, including a special government employee, shall knowingly act as agent or attorney for anyone other than United States in connection with any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, or other particular matter involving a specific party or parties in which the United States is a party or has a direct and substantial interest and in which he participated personally and substantially through decision, approval, disapproval, recommendation, rendering of advice, investigation, or otherwise as a Food and Drug Administration employee.

PART 20—PUBLIC INFORMATION

Subpart A—Official Testimony and Information

Sec.
20.1 Testimony by Food and Drug Administration employees.
20.2 Production of records by Food and Drug Administration employees.
20.3 Certification and authentication of Food and Drug Administration records.

Subpart B—General Policy

20.20 Policy on disclosure of Food and Drug Administration records.
20.21 Uniform access to records.
20.22 Partial disclosure of records.
20.23 Request for existing records.
20.24 Preparation of new records.
20.25 Retroactive application of regulations.
20.26 Indexes of certain records.
20.27 Submission of records marked as confidential.
20.28 Food and Drug Administration determinations of confidentiality.
20.29 Prohibition on withdrawal of records from Food and Drug Administration files.
20.30 Food and Drug Administration Freedom of Information Staff.
20.31 Retention schedule of requests for Food and Drug Administration records.
20.32 Disclosure of Food and Drug Administration employee names.

Subpart C—Procedures and Fees

20.40 Filing a request for records.
20.41 Time limitations.
20.42 Fees.
20.43 Waiver of fees.
20.44 Presubmission review of request for confidentiality of voluntarily submitted data or information.
20.45 Situations in which confidentiality is uncertain.
20.46 Judicial review of proposed disclosure.
20.47 Denial of a request for records.
20.48 Nonspecific and overly burdensome requests.
20.49 Referral to primary source of records.
20.50 Availability of records at National Technical Information Service.
20.51 Use of private contractor for copying.
20.52 Request for review without copying.
20.53 Indexing trade secrets and confidential commercial or financial information.

Subpart D—Exemptions

20.60 Applicability of exemptions.

Sec.
20.61 Trade secrets and commercial or financial information which is privileged or confidential.
20.62 Inter- or intra-agency memoranda or letters.
20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.
20.64 Investigatory records compiled for law enforcement purposes.

Subpart E—Limitations on Exemptions

20.80 Applicability of limitations on exemptions.
20.81 Data and information previously disclosed to the public.
20.82 Discretionary disclosure by the Commissioner.
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20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.
20.85 Disclosure to other Federal government departments and agencies.
20.86 Disclosure in administrative or court proceedings.
20.87 Disclosure to Congress.
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Subpart F—Availability of Specific Categories of Records

20.100 Applicability; cross-reference to other regulations.
20.101 Administrative enforcement records.
20.102 Court enforcement records.
20.103 Correspondence.
20.104 Summaries of oral discussions.
20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.
20.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.
20.107 Food and Drug Administration manuals.
20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.
20.109 Data and information obtained by contract.
20.110 Data and information about Food and Drug Administration employees.
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20.111 Data and information submitted voluntarily to the Food and Drug Administration.
20.112 Voluntary drug experience reports submitted by physicians and hospitals.
20.113 Voluntary product defect reports.
20.114 Data and information submitted pursuant to cooperative quality assurance agreements.
20.115 Product codes for manufacturing or sales dates.
20.116 Drug and device listing information.
20.117 New drug information.
20.118 Advisory committee records.
20.119 Lists of names and addresses.

AUTHORITY: Sec. 201 *et seq.*, Pub. L. 717, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321 *et seq.*); sec. 1 *et seq.*, Pub. L. 410, 58 Stat. 682 *et seq.*, as amended (42 U.S.C. 201 *et seq.*); Pub. L. 90-23, 81 Stat. 54-56 as amended by 88 Stat. 1561-1565 (5 U.S.C. 552); 21 CFR 5.10, 5.11.

SOURCE: 42 FR 15616, Mar. 22, 1977, unless otherwise noted.

Subpart A—Official Testimony and Information

§ 20.1 Testimony by Food and Drug Administration employees.

(a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health and Human Services, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information acquired in the discharge of his official duties.

(b) Whenever a subpoena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the grounds that it is prohibited by this section.

(c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request: *Provided*, That a written request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto.

§ 20.2 Production of records by Food and Drug Administration employees.

(a) Any request for records of the Food and Drug Administration, whether it be by letter or by a subpena duces tecum or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part, and shall comply with the rules governing public disclosure established in Subparts C, D, E, and F of this part and in other regulations cross-referenced in § 20.100(c).

(b) Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any record, such officer or employee shall appear in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part.

§ 20.3 Certification and authentication of Food and Drug Administration records.

(a) Upon request, the Food and Drug Administration will certify the authenticity of copies of records that are requested to be disclosed pursuant to this part or will authenticate copies of records previously disclosed.

(b) A request for certified copies of records or for authentication of records shall be sent in writing to the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

Subpart B—General Policy

§ 20.20 Policy on disclosure of Food and Drug Administration records.

(a) The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) Except where specifically exempt pursuant to the provisions of this part, all Food and Drug Administration records shall be made available for public disclosure.

(c) Except as provided in paragraph (d) of this section, all nonexempt records shall be made available for public disclosure upon request regardless whether any justification or need for such records have been shown.

(d) Under § 21.71 of this chapter, a statement of the purposes to which the record requested is to be put, and a certification that the record will be so used, may be requested when:

(1) The requested record is contained in a Privacy Act Record System as defined in § 21.3(c) of this chapter;

(2) The requester is a person other than the individual who is the subject of the record that is so retrieved or a person acting on his behalf; and

(3) The disclosure is one that is discretionary, i.e., not required under this part.

§ 20.21 Uniform access to records.

Any record of the Food and Drug Administration that is disclosed in an authorized manner to any member of the public is available for disclosure to all members of the public, except that:

(a) Data and information subject to the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information, and in § 20.63 for personal privacy, shall be disclosed only to the persons for the protection of whom these exemptions exist.

(b) The limited disclosure of records permitted in § 7.87(c) of this chapter for section 305 hearing records, in § 20.80(b) regarding certain limitations on exemptions, in § 20.103(b) for certain correspondence, and in § 20.104(b) for certain summaries of oral discussions, shall be subject to the special rules stated therein.

(c) Disclosure of a record about an individual as defined in § 21.3(a) of this chapter, that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter, shall be subject to the special requirements of Part 21 of this chapter. Disclosure of such a record to an individual who is the subject of the record does not invoke the rule established in this section that such records shall be made available for disclosure to all members of the public.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9037, Mar. 3, 1989]

§ 20.22 Partial disclosure of records.

If a record contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the remaining record will be disclosed unless the two are so inextricably intertwined that it is not feasible to separate them or release of the disclosable information would compromise or impinge upon the nondisclosable portion of the record.

§ 20.23 Request for existing records.

(a) Any written request to the Food and Drug Administration for existing records not prepared for routine distribution to the public shall be deemed to be a request for records pursuant to the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request, and shall be governed by the provisions of this part.

(b) Records or documents prepared by the Food and Drug Administration for routine public distribution, e.g., pamphlets, speeches, and educational materials, shall be furnished free of charge upon request as long as the supply lasts. The provisions of this part shall not be applicable to such requests except when the supply of such material is exhausted and it is necessary to reproduce individual copies upon specific request.

(c) All existing Food and Drug Administration records are subject to routine destruction according to standard record retention schedules.

§ 20.24 Preparation of new records.

(a) The Freedom of Information Act and the provisions of this part apply only to existing records that are reasonably described in a request filed with the Food and Drug Administration pursuant to the procedures established in Subpart C of this part.

(b) The Commissioner may, in his discretion, prepare new records in order to respond adequately to a request for information when he concludes that it is in the public interest and promotes the objectives of the act and the agency.

§ 20.25 Retroactive application of regulations.

The provisions of this part apply to all records in Food and Drug Administration files.

§ 20.26 Indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, for the following Food and Drug Administration records:

(1) Final orders published in the FEDERAL REGISTER with respect to every denial or withdrawal of approval of a new drug application or a new animal drug application for which a public hearing has been requested.

(2) Statements of policy and interpretation adopted by the agency and

still in force and not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(b) A copy of each such index is available at cost from the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.27 Submission of records marked as confidential.

Marking records submitted to the Food and Drug Administration as confidential, or with any other similar term, raises no obligation by the Food and Drug Administration to regard such records as confidential, to return them to the person who has submitted them, to review them pursuant to the procedures established in § 20.44, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed.

§ 20.28 Food and Drug Administration determinations of confidentiality.

A determination that data or information submitted to the Food and Drug Administration will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 20.44.

§ 20.29 Prohibition on withdrawal of records from Food and Drug Administration files.

Except pursuant to the procedure established in § 20.44 for presubmission review of records, no person may withdraw records submitted to the Food and Drug Administration. All Food and Drug Administration records shall be retained by the agency until disposed of pursuant to routine record disposal procedures.

§ 20.30 Food and Drug Administration Freedom of Information Staff.

(a) The Office responsible for agency compliance with the Freedom of Information Act and this part is:

Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

(b) All requests for agency records shall be sent in writing to this office.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.31 Retention schedule of requests for Food and Drug Administration records.

(a) Unless unusual circumstances dictate otherwise, the Food and Drug Administration shall maintain and dispose of files of requests and reponses furnished thereto within the time limits authorized by GSA General Records Schedule 14, FPMR 101-11-4, January 10, 1977, as follows:

(1) Files created by the receipt of and response to freedom of information requests, except denials and/or appeals, may be destroyed 2 years from date of final response.

(2) Files created by a freedom of information request which was wholly or partially denied may be destroyed 5 years after the denial letter was issued.

(3) Files created by a freedom of information request which was wholly or partially denied and which denial was subsequently appealed to the Department of Health and Human Services may be destroyed 4 years after final determination by FDA or 3 years after final adjudication by courts, whichever is later.

(b) This destruction schedule will automatically be revised whenever the time limits pertaining to these records are revised by the GSA General Records Schedule.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[47 FR 24277, June 4, 1982]

§ 20.32 Disclosure of Food and Drug Administration employee names.

The names of Food and Drug Administration employees will not be deleted from disclosable records except where such deletion is necessary to prevent disclosure of an informant or danger to the life or physical safety of the employee or under other extraordinary circumstances.

Subpart C—Procedures and Fees

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be filed in writing by mailing the request or delivering it to the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

(b) A request for Food and Drug Administration records shall reasonably describe the records being sought, in a way that they can be identified and located. A request should include all pertinent details that will help identify the records sought.

(1) If the description is insufficient to locate the records requested, the Food and Drug Administration will so notify the person making the request and indicate the additional information needed to identify the records requested.

(2) Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought.

(c) Upon receipt of a request for records, the Freedom of Information Staff shall enter it in a public log. The log shall state the date received, the name of the person making the request, the nature of the record requested, the action taken on the request, the date of determination letter sent pursuant to § 20.41(b), and the date(s) any records are subsequently furnished.

(d) A request by an individual, as defined in § 21.3(a) of this chapter, for a record about himself shall be subject to:

(1) The special requirements of Part 21 of this chapter (the privacy regulations), and not to the provisions of this subpart, if the record requested is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System, as defined in § 21.3(c) of this chapter.

(2) The provisions of this subpart if the record requested is not retrieved by the individual's name or other personal identifier, whether or not the record is contained in a Privacy Act Record System.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.41 Time limitations.

(a) All time limitations prescribed pursuant to this section shall begin as of the time at which a request for records is logged in by the Freedom of Information Staff pursuant to § 20.40(c). An oral request for records shall not begin any time requirement. A written request for records sent elsewhere within the agency shall not begin any time requirement until it is redirected to the Freedom of Information Staff and is logged in there in accordance with § 20.40(c).

(b) Within 10 working days (excepting Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Freedom of Information Staff, a letter shall be sent to the persons making the request determining whether, or to the extent which, the agency will comply with the request, and, if any records are denied, the reasons therefor.

(1) If all of the records requested have been located and a final determination has been made with respect to disclosure of all of the records requested, the letter shall so state.

(2) If all of the records have not been located or a final determination has not yet been made with respect to disclosure of all of the records requested, e.g., because it is necessary to consult the person affected pursuant to § 20.45, the letter shall state the extent to which the records involved shall be disclosed pursuant to the rules established in this part.

(3) In the following unusual circumstances, the time for sending this letter may be extended for up to an additional 10 working days by written notice to the person making the request setting forth the reasons for such extension and the time within which a determination is expected to be dispatched:

(i) The need to search for and collect the requested records from field facilities or other establishments that are separate from the Freedom of Information Staff.

(ii) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request.

(iii) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the Food and Drug Administration having substantial subject-matter interest therein.

(4) If any record is denied, the letter shall state the right of the person requesting such records to appeal any adverse determination to the Assistant Secretary for Health, Department of Health and Human Services, in accordance with the provisions of 45 CFR 5.82.

(5) If the request for records will result in a fee of more than $25.00, the letter shall specify or estimate the fee involved and shall require prepayment, as well as payment of any amount not yet received as a result of any previous request, before the records are made available. If the fee is less than $25.00, prepayment shall not be required unless payment has not yet been received for records disclosed as a result of a previous request.

(c) Whenever possible, the determination letter required by paragraph (b) of this section, relating to a request for records that involves a fee of less than $25.00, shall be accompanied by the requested records. Where this is not possible, the records shall be forwarded as soon as possible thereafter, consistent with other obligations of the agency.

(d) For requests for records involving a fee of more than $25.00, the records shall be forwarded as soon as possible after receipt of prepayment from the person requesting the records, consistent with other obligations of the agency.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.42 Fees.

(a) Unless waived in accordance with the provisions of § 20.43, the following fees shall be imposed for disclosure of any record pursuant to this part.

(1) *Copying of records.* Ten cents per copy of each page.

(2) *Copying of microfilm or microfiche.* Fifty cents per microfilm frame or microfiche.

(3) *Computerized records.* The sum of the actual costs of:

(i) The computer time involved, based upon the prevailing level of cost to government organizations and upon the particular types of computer and associated equipment and the amounts of time on such equipment that are utilized.

(ii) The supplies or materials necessary to produce the requested records.

(iii) The services of the personnel in accordance with paragraph (a)(4) and (5) of this section.

(4) *Clerical searches.* $3.00 for each hour spent by clerical personnel searching for and producing a requested record, including time spent copying any record.

(5) *Nonclerical searches.* $3.00 for each hour spent by professional or managerial personnel searching for and producing a requested record, including time spent copying any record.

(6) *Certification or authentication of records.* $3.00 per certification or authentication.

(7) *Forwarding material to destination.* Postage, insurance, and special fees will be charged on an actual cost basis.

(b) No charge shall be made for the time spent in resolving legal or policy issues or in examining records for the purpose of deleting nondisclosable portions thereof.

(c) Payment shall be made by check or money order payable to "Food and Drug Administration," and shall be sent to the Accounting Branch (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9037, Mar. 3, 1989]

§ 20.43 Waiver of fees.

(a) No fee shall be charged for disclosure of records pursuant to this part where:

(1) The cost of providing the records is less than $5.00. In making this determination, the cost of other requests by the same individual or organization, or related individuals or organizations, shall be aggregated.

(2) The records are requested by a congressional committee or subcommittee or the General Accounting Office.

(3) The records are requested by a Federal department or agency.

(4) The records are requested by a Federal court.

(5) The records are requested by a foreign government or by a State or local government or any agency thereof for purposes that are in the public interest and will promote the objectives of the act and the agency.

(b) The Associate Commissioner for Public Affairs may waive payment of fees when he or she determines, based upon a petition, that the person making the request for records is indigent and that the disclosure has a strong public interest justification. All statements made in any such petition are subject to the False Reports to the Government Act, 18 U.S.C. 1001. A person shall be deemed to be indigent for the purposes of this section if he or she does not have income or resources sufficient to pay the fees involved. Determinations pursuant to this provision will be made within the discretion of the agency.

(c) The Associate Commissioner for Public Affairs may reduce or waive payment of fees when he or she determines, based upon a verified petition, that such reduction or waiver is in the public interest because furnishing the information can be considered primarily as benefiting the general public.

(1) Any such petition shall contain a statement of the intended purpose to which the records requested will be put, showing how it will primarily benefit the general public, and, if the total fee would otherwise exceed $25.00, a statement of the reason why the volume of records requested is necessary and a statement of the income and financial resources available to the person making the request.

(2) The Associate Commissioner for Public Affairs may make available part of the records requested, or different records from those requested, in response to any such request for waiver of fees where he or she concludes that such records adequately meet that part of the request which is in the public interest.

(3) In making a determination of the broad public interest involved, the Associate Commissioner for Public Affairs will weigh the agency resources involved against the likely benefit to the public.

(4) Determinations pursuant to this provision will be made within the discretion of the agency.

(d) No fee shall be charged if a record requested is not found or for any record that is totally exempt from disclosure.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8456, Jan. 27, 1981]

§ 20.44 Presubmission review of request for confidentiality of voluntarily submitted data or information.

(a) Any person who is considering submission of data or information voluntarily to the Food and Drug Administration may forward to the Director of the Center involved, or to the Associate Commissioner for Regulatory Affairs, a request for presubmission review of the records involved to determine whether the Food and Drug Administration will or will not make part or all of them available for public disclosure upon request if they are submitted. Any such request shall state why the data or information involved fall within an exemption from public disclosure set out in Subpart D of this part and shall enclose the records involved.

(b) Pending a determination upon such request, the records involved shall be held confidentially and separately by the Food and Drug Administration and shall not be received as part of Food and Drug Administration files.

(c) Pursuant to such a request, the Food and Drug Administration shall make a determination whether part or all of the records involved will be made available for public disclosure upon request if they are submitted. A determination of confidentiality will be made only if it is concluded that the data or information involved fall within an exemption from public disclosure set out in Subpart D of this part and are relevant to and important for agency activity.

(d) After a determination is made pursuant to this section, the Food and Drug Administration shall receive as part of its files the records for which a request for confidentiality has been granted and shall so mark or designate those records. The person requesting the presubmission review shall have the option of submitting or withdrawing the records for which a request for confidentiality has been denied. No copy or summary of records withdrawn pursuant to this section, or any correspondence or memoranda or records relating thereto, shall be retained in Food and Drug Administration files.

(e) A determination of confidentiality pursuant to this section is subject to the limitations established in Subpart E of this part except that the data or information involved shall not be subject to discretionary release pursuant to § 20.82. Such a determination of confidentiality by the Food and Drug Administration means that the Food and Drug Administration will not make the data or information involved available for public disclosure unless ordered to do so by a court.

(f) A determination based upon a presubmission review pursuant to this section shall be made in writing and shall be signed only by the Associate Commissioner for Public Affairs.

(g) Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(h) No request under this section shall be accepted if the status of the records involved is already determined by § 20.111 or by any other regulation published or cross-referenced in this part.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 50 FR 8995, Mar. 6, 1985]

§ 20.45 Situations in which confidentiality is uncertain.

In situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, the Food and Drug Administration will consult with the person who has submitted or divulged the data or information or who would be affected by disclosure before determining whether or not such data or information is available for public disclosure.

§ 20.46 Judicial review of proposed disclosure.

Where the Food and Drug Administration consults with a person who will be affected by a proposed disclosure of data or information contained in Food and Drug Administration records pursuant to § 20.45, and rejects the person's request that part or all of the records not be made available for public disclosure, the decision constitutes final agency action that is subject to judicial review pursuant to 5 U.S.C. chapter 7. The person affected will be permitted 5 days after receipt of notification of such decision within which to institute suit in a United States District Court to enjoin release of the records involved. If suit is brought, the Food and Drug Administration will not disclose the records involved until the matter and all related appeals have been concluded.

§ 20.47 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Associate Commissioner for Public Affairs.

(b) The name and title or position of each person who participated in the denial of a request for records shall be set forth in the letter denying the request. This requirement may be met by attaching a list of such individuals to the letter.

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Assistant Secretary for Health, Department of Health and Human Services, pursuant to the provisions of 45 CFR 5.82.

(d) Minor deletions of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981]

§ 20.48 Nonspecific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply fully with all requests for disclosure of nonexempt records. Nonspecific requests or requests for a large number of documents that require the deployment of a substantial amount of agency man-hours to search for and compile will be processed taking into account the staff-hours required, the tasks from which these resources must be diverted, the impact that this diversion will have upon the agency's consumer protection activities, and the public policy reasons justifying the requests. A decision on the processing of such a request for information shall be made after balancing the public benefit to be gained by the disclosure against the public loss that will result from diverting agency personnel from their other responsibilities. In any situation in which it is determined that a request for voluminous records would unduly burden and interfere with the operations of the Food and Drug Administration, the person making the request will be asked to be more specific and to narrow the request, and to agree on an orderly procedure for the production of the requested records, in order to satisfy the request without disproportionate adverse effects on agency operations.

§ 20.49 Referral to primary source of records.

Upon receipt of a request for a record or document which is contained in Food and Drug Administration files but which is available elsewhere at a lower cost, the person requesting the record or document shall be referred to the primary source of the record or document.

§ 20.50 Availability of records at National Technical Information Service.

The Food and Drug Administration is furnishing a number of records to the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22162, which reproduces and distributes such information to the public at cost. A single copy of each such record shall be available for public review at the Food and Drug Administration. All persons requesting copies of such records shall be answered by referring the person requesting the records to NTIS.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

§ 20.51 Use of private contractor for copying.

The Food and Drug Administration may furnish requested records to a private contractor for copying after deletion of all nondisclosable data and information. Under these circumstances, the Food and Drug Administration will charge the person requesting the records for all of the fees involved pursuant to § 20.42.

§ 20.52 Request for review without copying.

(a) A person requesting disclosure of records shall be permitted an opportunity to review them without the necessity for copying them where the records involved contain only disclosable data and information. Under these circumstances, the Food and Drug Administration will charge only for the costs of searching for the records.

(b) Where a request is made for review of records without copying, and the records involved contain both disclosable and nondisclosable information, the records containing nondisclosable information shall first be copied with the nondisclosable information blocked out and the Food and Drug Administration will charge for the costs of searching and copying.

§ 20.53 Indexing trade secrets and confidential commercial or financial information.

Whenever the Food and Drug Administration denies a request for a record or portion thereof on the grounds that the record or portion thereof is exempt from public disclosure as trade secret or confidential commercial or financial data and information under § 20.61, and the person requesting the record subsequently contests the denial in the courts, the Food and Drug Administration will so inform the person affected, i.e., the person who submitted the record, and will require that such person intervene to defend the exempt status of the record. If a court requires the Food and Drug Administration to itemize and index such records, the Food and Drug Administration will so inform the person affected and will require that such person undertake the itemization and indexing of the records. The failure of the affected person to intervene to defend the exempt status of the records and to itemize and index the disputed records will constitute a waiver by such person of such exemption, and the Food and Drug Administration will promptly make them available for public disclosure.

Subpart D—Exemptions

§ 20.60 Applicability of exemptions.

(a) The exemptions established in this subpart shall apply to all Food and Drug Administration records, except as provided in Subpart E of this part. Accordingly, a record that is ordinarily available for public disclosure in accordance with the provisions in Subpart F of this part or of another regulation cross-referenced in § 20.100(c) is not available for such disclosure to the extent that it falls within an exemption contained in this subpart, except as provided by the limitations on exemptions specified in Subpart E of this part. For example, correspondence that is ordinarily disclosable under § 20.103 is not disclosable to the extent that it contains trade secrets exempt from disclosure under § 20.61 and is not subject to discretionary release under § 20.82.

(b) Where application of one or more exemptions results in a record being disclosable in part and nondisclosable in part, the rule established in § 20.22 shall apply.

§ 20.61 Trade secrets and commercial or financial information which is privileged or confidential.

(a) A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.

(b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

(c) Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

§ 20.62 Inter- or intra-agency memoranda or letters.

All communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure.

§ 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.

(b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(c) Requests for deletion of business or product names prior to disclosure of any record to the public shall not be granted on the ground of privacy, but such deletion may be justified under another exemption established in this subpart, e.g., the exemption for trade secrets and confidential commercial or financial information under § 20.61.

(d) Names of individuals conducting investigations, studies, or tests on products or ingredients shall not be deleted prior to disclosure of any record to the public unless extraordinary circumstances are shown.

(e) A request for all records relating to a specific individual will be denied as a clearly unwarranted invasion of personal privacy unless accompanied by the written consent of the individual named.

§ 20.64 Investigatory records compiled for law enforcement purposes.

(a) An investigatory record for law enforcement purposes may be withheld from public disclosure pursuant to the provisions of this section to the extent that disclosure of such records would:

(1) Interfere with enforcement proceedings.

(2) Deprive a person of a right to a fair trial or an impartial adjudication.

(3) Constitute an unwarranted invasion of personal privacy.

(4) Disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source.

(5) Disclose investigative techniques and procedures.

(6) Endanger the life or physical safety of law enforcement personnel.

(b) Investigatory records include all records relating to regulatory enforcement action, including both administrative and court action, which have not been disclosed to any member of the public, including any person who is the subject of the investigation.

(c) Any investigatory record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in Subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of § 7.87 of this chapter.

(d) Investigatory records for law enforcement purposes shall be subject to the following rules:

(1) No such record is available for public disclosure prior to the consideration of regulatory enforcement action based upon that record's being closed, except as provided in § 20.82. The Commissioner will exercise his discretion to disclose records relating to possible criminal prosecution pursuant to § 20.82 prior to consideration of criminal prosecution being closed only very rarely and only under circumstances that demonstrate a compelling public interest.

(2) After the consideration of regulatory enforcement action is closed, such records shall be made available for public disclosure except to the extent that other exemptions from disclosure in this subpart are applicable. No statements of witnesses obtained through promises of confidentiality are available for public disclosure.

(3) The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section:

(i) If it relates to administrative action, when a final decision has been made not to take such action or such action has been taken and the matter has been concluded.

(ii) If it relates to court action, when a final decision has been made not to recommend such action to a United States attorney based upon that record, or a recommendation has been finally refused by a United States attorney, or court action has been instituted and the matter and all related appeals have been concluded, or the statute of limitations runs.

(iii) If it relates to both administrative and court action, when the events described in both paragraph (d)(3) (i) and (ii) of this section have occurred.

(4) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(e) Names and other information that would identify a Food and Drug Administration employee shall be deleted from investigatory records prior to public disclosure only pursuant to § 20.32.

Subpart E—Limitations on Exemptions

§ 20.80 Applicability of limitations on exemptions.

(a) The limitations on exemptions established in this subpart shall apply to all Food and Drug Administration records, except as specifically provided herein. Accordingly, a record that is ordinarily exempt from public disclosure in accordance with the provisions in Subpart D of this part is available for such disclosure to the extent that it falls within a limitation on the exemption contained in this subpart. For example, an investigatory record that is ordinarily exempt from disclosure under § 20.64 is disclosable to Congress in accordance with the provisions of § 20.87.

(b) Disclosure of a record to any member of the public pursuant to the provisions in § 20.81, data and information previously disclosed to the public, in § 20.82, discretionary disclosure by the Commissioner, and in § 20.83, disclosure pursuant to a court order, shall involve the rule established in § 20.21 that the record shall be made available for disclosure to all members of the public who request it. Disclosure of a record only to the limited categories of persons and under the conditions specified in § 20.84, special government employees, in § 20.85, other Federal government departments and agencies, in § 20.86, in camera disclosure in administrative or court proceedings, in § 20.87(b), Congress, in § 20.88, State and local government officials, in § 20.89, foreign government officials, and in § 20.90, contractors, which does not result in disclosure of the record to any member of the public in an authorized manner, shall not invoke the rule established in § 20.21.

(c) Disclosure to government employees and special government employees of records exempt from public disclosure shall subject those persons to the same restrictions with respect to the disclosure of such records as any Food and Drug Administration employee.

(d) In the case of a record in a Privacy Act Record System, as defined in § 21.3(c) of this chapter:

(1) The availability to an individual, as defined in § 21.3(a), of a record about himself that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System shall be subject to the special requirements of Part 21 of this chapter (the privacy regulations) and shall not be subject to the exemptions in Subpart D of this part except that where the system is exempt and the requested record is not available under § 21.61 of this chapter, the provisions of this part shall apply.

(2) The availability of a record about an individual to persons other than the individual who is the subject of the record shall be subject to the special requirements of Part 21, Subpart G, of this chapter (restrictions on disclosure in the privacy regulations), and shall not be subject to the limitations on exemptions in this subpart

except as provided in Part 21, Subpart G, of this chapter.

§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to Subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commerical arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) For purposes of this section, other commercial arrangements shall include licenses, contracts, and similar legal relationships between business associates.

(3) For purposes of this section, data and information disclosed to clinical investigators or members of institutional review committees, whether required by Part 312 of this chapter or other regulations of the Food and Drug Administration, or made voluntarily, if accompanied by appropriate safeguards to assure secrecy and otherwise in accordance with this section, are not deemed to have been previously disclosed to any member of the public within the meaning of paragraph (a) of this section.

(b) Any data or information furnished to the Food and Drug Administration for a presubmission review pursuant to the procedure established in § 20.44 shall be accompanied by a statement that the information has not previously been published or disclosed to anyone other than as provided in paragraph (a) of this section.

(c) Any statement relating to prior public disclosure is subject to the False Reports to the Government Act, 18 U.S.C. 1001.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

§ 20.82 Discretionary disclosure by the Commissioner.

(a) Except as provided in paragraph (b) of this section, the Commissioner may, in his discretion, disclose part or all of any Food and Drug Administration record that is otherwise exempt from disclosure pursuant to Subpart D of this part. The Commissioner shall exercise his discretion to disclose such records whenever he determines that such disclosure is in the public interest, will promote the objectives of the act and the agency, and is consistent with the rights of individuals to privacy, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) The Commissioner shall not make available for public disclosure any record that is:

(1) Exempt from public disclosure pursuant to § 20.61.

(2) Exempt from public disclosure pursuant to § 20.63.

(3) Prohibited from public disclosure pursuant to 21 U.S.C. 331(j), 42 U.S.C. 263g(d), 42 U.S.C. 263i, or 18 U.S.C. 1905.

(4) Contained in a Privacy Act Record System where disclosure would constitute a clearly unwarranted invasion of personal privacy or is otherwise in violation of 5 U.S.C. 552a(b), as applied in Part 21, Subpart G, of this chapter (restrictions on disclosure in the privacy regulations).

(c) Discretionary disclosure of a record pursuant to this section shall invoke the requirement that the record shall be disclosed to any person who requests it pursuant to § 20.21, but shall not set a precedent for discretionary disclosure of any similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record that is exempt from disclosure.

§ 20.83 Disclosure required by court order.

(a) Records of the Food and Drug Administration which the Commissioner has determined are not available for public disclosure, either in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 20.44, shall nevertheless be made available for public disclosure in compliance with a final court order requiring such disclosure.

(b) Where the Food and Drug Administration record ordered disclosed under paragraph (a) of this section is a record about an individual that is not available for public disclosure under § 20.63, the Food and Drug Administration shall attempt to notify the individual who is the subject of the record of the disclosure, by sending a notice to the individual's last known address.

(c) Paragraph (b) of this section shall not apply where the name or other personal identifying information is deleted prior to disclosure.

§ 20.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

§ 20.85 Disclosure to other Federal government departments and agencies.

Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and confidential commercial or financial information prohibited from disclosure by 21 U.S.C. 331(j), 21 U.S.C. 360(j)(c), 42 U.S.C. 263g(d) and 42 U.S.C. 263i(e) may be released only as provided by those sections. Any disclosure under this section shall be pursuant to an agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.

[47 FR 10804, Mar. 12, 1982]

§ 20.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to Parts 10, 12, 13, 14, 15, 16, and 19 of this chapter or court proceedings, where the data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

§ 20.87 Disclosure to Congress.

(a) All records of the Food and Drug Administration shall be disclosed to Congress upon an authorized request, except for trade secrets prohibited by 21 U.S.C. 331(j) from disclosure outside the Department of Health and Human Services.

(b) An authorized request for Food and Drug Administration records by Congress shall be made by the chairman of a committee or subcommittee of Congress acting pursuant to committee business.

(c) An individual member of Congress who requests a record for his own use or on behalf of any constituent shall be subject to the same rules in this part that apply to any other member of the public.

§ 20.88 Communications with State and local government officials.

(a) A State or local government official commissioned by the Food and Drug Administration pursuant to 21 U.S.C. 372(a) shall have the same status with respect to disclosure of Food and Drug Administration records as any special government employee.

(b) Communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract between the Food and Drug Administration and such officials shall be subject to the rules for public disclosure established in § 20.64.

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administratrion at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

§ 20.89 Communications with foreign government officials.

Communications with foreign government officials shall have the same status as communications with any member of the public, except that:

(a) Investigatory records compiled for law enforcement purposes by foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration as part of cooperative law enforcement and regulatory efforts, shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 20.61 and 20.64, as if they had been prepared by or submitted directly to Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the foreign government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(b) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country as part of cooperative law enforcement efforts does not invoke the rule established in § 20.21 that such records shall be made available for disclosure to all members of the public.

§ 20.90 Disclosure to contractors.

(a) Data and information otherwise exempt from public disclosure may be disclosed to contractors with the Food and Drug Administration and their employees for use only in their work for the Food and Drug Administration. Contractors and their employees are thereafter subject to the same legal restrictions and penalties with respect to the disclosure of such data and information as Food and Drug Administration employees.

(b) A written agreement between the Food and Drug Administration and any contractor shall be entered into before data and information otherwise exempt from public disclosure may be disclosed to the contractor. The contractor shall agree to establish and follow security precautions considered by the Food and Drug Administration to be necessary to ensure proper and confidential handling of the data and information. The written agreement shall include, where appropriate, provisions establishing:

(1) Restrictions on access to the data and information by the contractor, its employees, or other persons;

(2) Physical storage requirements;

(3) Requirements for the handling and accountability of the data and information by the contractor and its employees;

(4) Limitations on reproduction, transmission, and disclosure of the data and information;

(5) A requirement of advance approval by the Food and Drug Administration of the use by the contractor of subcontractors, vendors, or suppliers;

(6) Procedures to be followed when the contractor employs time-shared computer operations;

(7) Methods of destroying source documents or related waste material; and

(8) The period during which the contractor may retain such data and information.

§ 20.91 Use of data or information for administrative or court enforcement action.

Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled.

Subpart F—Availability of Specific Categories of Records

§ 20.100 Applicability; cross reference to other regulations.

(a) The provisions set forth in this subpart or cross-referenced in paragraph (c) of this section state the way in which specific categories of Food and Drug Administration records are handled upon a request for public disclosure. The exemptions established in Subpart D of this part and the limitations on exemptions established in Subpart E of this part shall be applicable to all Food and Drug Administration records, as provided in §§ 20.60 and 20.80. Accordingly, a record that is ordinarily available for public disclosure in accordance with this part or under other regulations is not available for such disclosure to the extent that it falls within an exemption contained in Subpart D of this part except as provided by the limitations on exemptions specified in Subpart E of this part.

(b) The Commissioner, on his own initiative or on the petition of any interested person, may amend this subpart or promulgate and cross-reference additional regulations to state the status of additional categories of documents to settle pending questions or to reflect court decisions.

(c) In addition to the provisions of this part, rules on the availability of the following specific categories of Food and Drug Administration records are established by regulations in this chapter:

(1) Section 305 hearing records, in § 7.87(c) of this chapter.

(2) Flavor ingredient records and notes, in § 101.22(i)(4)(iv) of this chapter.

(3) Environmental assessments; finding of no significant impact, in § 25.41 of this chapter, or draft and final environmental impact statements, in § 25.42 of this chapter.

(4) Color additive petitions, in § 71.15 of this chapter.

(5) Food standard temporary permits, in § 130.17(k) of this chapter.

(6) Information on thermal processing of low-acid foods packaged in her-

metically sealed containers, in § 108.35(l) of this chapter.

(7) Food additive petitions, in § 171.1(h) of this chapter.

(8) Action levels for natural and unavoidable defects in food for human use, in § 110.110(e) of this chapter.

(9) Drug establishment registrations and drug listings, in § 207.37 of this chapter.

(10) Investigational new animal drug notices, in § 514.12 of this chapter.

(11) New animal drug application files, in § 514.11 of this chapter.

(12) Investigational new animal drug notice and a new animal drug application file for an antibiotic drug, in § 514.10 of this chapter.

(13) Methadone patient records, in § 291.505(g) of this chapter.

(14) Investigational new drug notice, in Part 312 of this chapter.

(15) Labeling for and lists of approved new drug applications, in § 314.430 of this chapter.

(16) Master files for new drug applications, in § 314.420 of this chapter.

(17) New drug application file, in § 314.430 of this chapter.

(18) Data and information submitted for in vitro diagnostic products, in § 809.4 of this chapter.

(19) Data and information submitted for OTC drug review, in § 330.10(a)(2) of this chapter.

(20) Investigational new drug notice for an antibiotic drug, in § 431.70 of this chapter.

(21) Antibiotic drug file, in § 314.430 of this chapter.

(22) Data and information submitted for biologics review, in § 601.25(b)(2) of this chapter.

(23) Investigational new drug notice for a biological product, in § 601.50 of this chapter.

(24) Applications for establishment and product licenses for biological products, in § 601.51 of this chapter.

(25) Cosmetic establishment registrations, in § 710.7 of this chapter.

(26) Cosmetic product ingredient and cosmetic raw material composition statements, § 720.8 of this chapter.

(27) Cosmetic product experience reports, in § 730.7 of this chapter.

(28) Device premarket notification submissions, in § 807.95 of this chapter.

(29) Electronic product information, in §§ 1002.4 and 1002.42 of this chapter.

(30) Investigational device exemptions in § 813.38 of this chapter.

(31) Data and information submitted to the Commissioner or to classification panels in connection with the classification or reclassification of devices intended for human use, in § 860.5 of this chapter.

(32) Data and information submitted in offers to develop a proposed performance standard for medical devices, in § 861.26 of this chapter.

(33) Investigational device exemptions in § 812.38 of this chapter.

(Secs. 301, 501, 502, 513, 514, 515, 519, 520, 701, 702, 704, 801, 52 Stat. 1042-1043 as amended, 1049-1051 as amended, 1055, 1056-1058 as amended, 67 Stat. 476-477 as amended, 90 Stat. 540-559, 564-574, 576-578 (21 U.S.C. 331, 351, 352, 360, 360c, 360d, 360e, 360i, 360j, 371, 372, 374, 381))

[42 FR 15616, Mar. 22, 1977, as amended at 42 FR 19989, Apr. 15, 1977; 42 FR 42526, Aug. 28, 1977; 42 FR 58889, Nov. 11, 1977; 43 FR 32993, July 28, 1978; 51 FR 22475, June 19, 1986; 54 FR 9038, Mar. 3, 1989]

§ 20.101 Administrative enforcement records.

(a) All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory inspection, recall or detention requests, notice of refusal of admission of an imported product, regulatory letters, information letters, Forms FD-483 and FD-2275 furnished to companies after factory inspection, and similar records.

(b) To the extent that any of such records fall within the exemption for investigatory records established in § 20.64, the Commissioner determines that they are subject to discretionary release pursuant to § 20.82.

(c) Records relating to administrative enforcement action that are not disclosed to any member of the public constitute investigatory records that are subject to the rules for disclosure established in § 20.64. For example, an establishment inspection report is an investigatory record and thus subject to § 20.64 except insofar as the Commissioner exercises his discretion to release it pursuant to § 20.82.

§ 20.102 Court enforcement records.

(a) All records and documents filed in the courts are available for public disclosure unless the court orders otherwise. The Food and Drug Administration will make available for public disclosure such records or documents if the agency can determine that it has an accurate copy of the actual record or document filed in the court. If the Food and Drug Administration cannot determine whether it has an accurate copy of such a record or document, the person requesting a copy shall be referred to the court involved.

(b) After a recommendation for court action has been finally refused by a United States attorney, the correspondence with the United States attorney and the Department of Justice with respect to that recommendation, including the pleadings recommended for filing with the court, is available for public disclosure. Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

§ 20.103 Correspondence.

(a) All correspondence to and from members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal Government and special government employees, is available for public disclosure.

(b) Any such correspondence is available for public disclosure at the time that it is sent or received by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., correspondence relating to an IND notice or an NDA in § 314.430 of this chapter.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

§ 20.104 Summaries of oral discussions.

(a) All written summaries of oral discussions, whether in person or by telephone, with members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal government or special government employees, are available for public disclosure.

(b) Any such summary is available for public disclosure at the time that it is prepared by the Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., summaries of oral discussions relating to a food additive petition in § 171.1(h)(3) of this chapter.

(c) If more than one summary of an oral discussion exists in a Food and Drug Administration file, all such summaries shall be disclosed in response to any request for such summary.

§ 20.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.

(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

(b) Any contract relating to agency testing and research, and any progress report relating thereto, is available for public disclosure.

(c) The results of all testing or research conducted by or with funds provided by the Food and Drug Administration, such as toxicological testing, compliance assays, methodology studies, and product testing, are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official, after deletion of any information that would reveal confidential investigative techniques and procedures, e.g., the use of "markers" to document adulteration of a product. If such results are disclosed in an authorized manner to any member of the public before the final report is available, they are immediately available for public disclosure to any member of the public who requests them.

(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed.

§ 20.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.

(a) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are available for public disclosure upon their acceptance by the responsible agency official:

(1) Quarterly and annual reports of the agency.

(2) External investigations or review of agency needs and performance.

(3) Surveys, compilations, and summaries of data and information.

(4) Consumer surveys.

(5) Compliance surveys.

(6) Compliance programs, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the program is completed.

(7) Work plans prepared by Food and Drug Administration centers, field offices, and other components, except that names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be deleted until implementation of the plan is completed.

(b) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are not available for public disclosure:

(1) Internal audits of agency needs and performance.

(2) Records relating to the internal planning and budget process.

(3) Legislative proposals or comments prior to submission to Congress.

[42 FR FR 15616, Mar. 22, 1977, as amended at 50 FR 8995, Mar. 6, 1985]

§ 20.107 Food and Drug Administration manuals.

(a) All Food and Drug Administration Staff Manuals and instructions to staff that affect a member of the public are available for public disclosure. An index of all such manuals is available at the Food and Drug Administration's Freedom of Information Public Room in accordance with § 20.26.

(b) Manuals relating solely to internal personnel rules and practices are not available for public disclosure except to the extent that the Commissioner determines that they should be disclosed pursuant to § 20.82.

(c) All Food and Drug Administration action levels which are used to determine when the agency will take regulatory action against a violative product, limits of sensitivity and variability of analytical methods which are used in determining whether a product violates the law, and direct reference levels above which Food and Drug Administration field offices may request legal action directly to the office of the General Counsel, are available for public disclosure.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981]

§ 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

(a) All written agreements and understandings signed by the Food and Drug Administration and other departments, agencies, and organizations are available for public disclosure.

(b) A permanent file of all such agreements and understandings is available for public review during working hours in the Food and Drug Administration's Freedom of Information Public Room.

(c) In accordance with the notice published in the FEDERAL REGISTER of October 3, 1974 (39 FR 35697), all such agreements and understandings shall be published in the FEDERAL REGISTER.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981]

§ 20.109 Data and information obtained by contract.

(a) All data and information obtained by the Food and Drug Administration by contract, including all progress reports pursuant to a contract, are available for public disclosure when accepted by the responsible agency official except to the extent that they remain subject to an exemption established in Subpart D of this part, e.g., they relate to law enforcement matters as provided in § 20.88(b).

(b) Upon the awarding of a contract by the Food and Drug Administration, the technical proposal submitted by the successful offeror will be available for public disclosure. All cost proposals and the technical proposals of unsuccessful offerors submitted in response to a request for proposals are exempt from disclosure as confidential commercial or financial information pursuant to § 20.61.

§ 20.110 Data and information about Food and Drug Administration employees.

(a) The name, title, grade, position description, salary, work address, and work telephone number for every Food and Drug Administration employee are available for public disclosure. The home address and home telephone number of any such employee are not available for public disclosure.

(b) Statistics on the prior employment experience of present agency employees, and subsequent employment of past agency employees, are available for public disclosure.

§ 20.111 Data and information submitted voluntarily to the Food and Drug Administration.

(a) The provisions of this section shall apply only to data and information submitted voluntarily to the Food and Drug Administration, whether in the course of a factory inspection or at any other time, and not as a part of any petition, application, master file, or other required submission or request for action. Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(b) A determination that data or information submitted voluntarily will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 20.44.

(c) The following data and information submitted voluntarily to the Food and Drug Administration are available for public disclosure unless extraordinary circumstances are shown:

(1) All safety, effectiveness, and functionality data and information for a marketed ingredient or product, except as provided in § 330.10(a)(2) of this chapter for OTC drugs.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established in § 20.61 for trade secrets and confidential commercial or financial information.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be disclosed as follows:

(i) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and other information that would identify the person submitting the information.

(ii) If submitted by the manufacturer of the product, the record is available for public disclosure after deletion of:

(*a*) Names and any information that would identify the person using the product.

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(*c*) Names and any other information that would identify the manufacturer or the brand designation of the product, but not the type of product or its ingredients.

(iii) If submitted by a third party, such as a physician or hospital or other institution, the record is available for public disclosure after deletion of:

(*a*) Names and any information that would identify the person using the product.

(*b*) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(iv) If obtained through a Food and Drug Administration investigation, the record shall have the same status as the initial report which led to the investigation, i.e., it shall be disclosed in accordance with paragraph (c)(3)(i) through (iii) of this section.

(v) Any compilation of data, information, and reports prepared in a way that does not reveal data or information which is not available for public disclosure under this section is available for public disclosure.

(vi) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report. The record will be disclosed to the individual who is the subject of the report upon request.

(4) A list of all ingredients contained in a food or cosmetic, whether or not it is in descending order of predominance, or a list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 20.81 contained in a drug, or a list of all ingredients or components in a device. A particular ingredient or component or group of ingredients or components shall be deleted from any such list for a cosmetic or device prior to public disclosure upon a determination made pursuant to § 20.44 that the ingredient or ingredients fall within the exemption established in § 20.61 for trade secrets and confidential commercial information, and a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61.

(d) The following data and information submitted voluntarily to the Food and Drug Administration are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61:

(1) All safety, effectiveness, and functionality data and information for a developmental ingredient or product that has not previously been disclosed to the public as defined in § 20.81.

(2) Manufacturing methods or processes, including quality control procedures.

(3) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(4) Quantitative or semiquantitative formulas.

(e) For purposes of this regulation, safety, effectiveness, and functionality data include all studies and tests of an ingredient or a product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

§ 20.112 Voluntary drug experience reports submitted by physicians and hospitals.

(a) A voluntary drug experience report to the Food and Drug Administration on Form FDA-1639 shall be handled in accordance with the rules established in § 20.111(c)(3)(iii).

(b) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

§ 20.113 Voluntary product defect reports.

Voluntary reports of defects in products subject to the jurisdiction of the Food and Drug Administration are available for public disclosure:

(a) If the report is submitted by the manufacturer, after deletion of data and information falling within the exemptions established in § 20.61 for trade secrets and confidential commercial or financial information and in § 20.63 for personal privacy.

(b) If the report is submitted by any person other than the manufacturer, after deletion of names and other information that would identify the person submitting the report and any data or information falling within the exemption established in § 20.63 for personal privacy.

§ 20.114 Data and information submitted pursuant to cooperative quality assurance agreements.

Data and information submitted to the Food and Drug Administration pursuant to a cooperative quality assurance agreement shall be handled in accordance with the rules established in § 20.111.

§ 20.115 Product codes for manufacturing or sales dates.

Data or information in Food and Drug Administration files which provide a means for deciphering or decoding a manufacturing date or sales date or use date contained on the label or in labeling or otherwise used in connection with a product subject to the jurisdiction of the Food and Drug Administration are available for public disclosure.

§ 20.116 Drug and device listing information.

Information submitted to the Food and Drug Administration pursuant to section 510 (a)-(j) of the act shall be subject only to the special disclosure provisions established in §§ 207.37 and 807.37 of this chapter.

(Secs. 301, 501, 502, 520, 701, 704, 801, 52 Stat. 1042-1043 as amended, 1049-1051 as amended, 1055, 90 Stat. 567, 569-571, 576-578 (21 U.S.C. 331, 351, 352, 360j, 371, 374, 381))

[42 FR 42526, Aug. 23, 1977]

§ 20.117 New drug information.

(a) The following computer printouts are available for public inspection in the Food and Drug Administration's Freedom of Information Public Room:

(1) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938, showing the NDA number, the trade name, the applicant, the approval date, and, where applicable, the date the approval was withdrawn and the date the Food and Drug Administration was notified that marketing of the product was discontinued.

(2) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938 which are still approved, showing the same information as is specified in paragraph (a)(1) of this section except that it does not show a withdrawal date.

(3) A listing of new drug applications, abbreviated new drug applications, antibiotic applications, which were approved since 1938 and which are still approved, covering marketed prescription drug products except prescription drug products covered by applications deemed approved under the Drug Amendments of 1962 and not yet determined to be effective in the Drug Efficacy Study Implementation program. The listing includes the name of the active ingredient, the type of dosage form, the route of administration, the trade name of the product, the name of the application holder, and the strength or potency of the product. The listing also includes, for each active ingredient in a particular dosage form for which there is more than one approved application, an evaluation of the therapeutic equivalence of the drug products covered by such applications.

(b) Other computer printouts containing IND and NDA information are available to the extent that they do not reveal data or information prohibited from disclosure under §§ 20.61, 312.130, and 314.430 of this chapter.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

[42 FR 15616, Mar. 22, 1977, as amended at 45 FR 72608, Oct. 31, 1980; 46 FR 8457, Jan. 27, 1981; 54 FR 9038, Mar. 3, 1989]

§ 20.118 Advisory committee records.

All advisory committee records shall be handled in accordance with the rules established in Parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

§ 20.119 Lists of names and addresses.

Names and addresses of individuals in Food and Drug Administration records shall not be sold or rented. Names and addresses shall not be disclosed if disclosure is prohibited as a clearly unwarranted invasion of personal privacy, e.g., lists of names and home addresses of Food and Drug Administration employees, which shall not be disclosed under § 20.110.

PART 21—PROTECTION OF PRIVACY

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AUTHORITY: Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)); 5 U.S.C. 552a; 21 CFR 5.10.

SOURCE: 42 FR 15626, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 21.1 Scope.

(a) This part establishes procedures to implement the Privacy Act of 1974 (5 U.S.C. 552a). It applies to records about individuals that are maintained, collected, used, or disclosed by the Food and Drug Administration and contained in Privacy Act Record Systems.

(b) This part does not:

(1) Apply to Food and Drug Administration record systems that are not Privacy Act Record Systems or make available to an individual records that may include references to him but that are not retrieved by his name or other personal identifier, whether or not contained in a Privacy Act Record System. Part 20 of this chapter (the public information regulations) and other regulations referred to therein

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determine when records are made available in such cases.

(2) Make any records available to persons other than (i) individuals who are the subjects of the records, (ii) persons accompanying such individuals under § 21.43, (iii) persons provided records pursuant to individual consent under § 21.72, or (iv) persons acting on behalf of such individuals as legal guardians under § 21.75. Part 20 of this chapter (the public information regulations) and other regulations referred to therein determine when Food and Drug Administration records are disclosable to members of the public generally. Subpart G of this part limits the provisions of Part 20 of this chapter with respect to disclosures of records about individuals from Privacy Act Record Systems to persons other than individuals who are the subjects of the records.

(3) Make available information compiled by the Food and Drug Administration in reasonable anticipation of court litigation or formal administrative proceedings. The availability of such information to any member of the public, including any subject individual or party to such litigation or proceeding shall be governed by applicable constitutional principles, rules of discovery, and Part 20 of this chapter (the public information regulations).

(4) Apply to personnel records maintained by the Division of Human Resources Management, Food and Drug Administration, except as provided in § 21.32. Such records are subject to regulations of the Office of Personnel Management in 5 CFR Parts 293, 294, and 297.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

§ 21.3 Definitions.

As used in this part:

(a) "Individual" means a natural living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. Individual does not include sole proprietorships, partnerships, or corporations engaged in the production or distribution of products regulated by the Food and Drug Administration or with which the Food and Drug Administration has business dealings. Any such business enterprise that is identified by the name of one or more individuals is not an individual within the meaning of this part. Employees of regulated business enterprises are considered individuals. Accordingly, physicians and other health professionals who are engaged in business as proprietors of establishments regulated by the Food and Drug Administration are not considered individuals; however, physicians and other health professionals who are engaged in clinical investigations, employed by regulated enterprises, or the subjects of records concerning their own health, e.g., exposure to excessive radiation, are considered individuals. Food and Drug Administration employees, consultants, and advisory committee members, State and local officials, and consumers are considered individuals.

(b) "Records about individuals" means items, collections, or groupings of information about individuals contained in Privacy Act Record Systems, including, but not limited to education, financial transactions, medical history, criminal history, or employment history, that contain names or personal identifiers.

(c) "Privacy Act Record System" means a system of records about individuals under the control of the Food and Drug Administration from which information is retrieved by individual names or other personal identifiers. The term includes such a system of records whether subject to a notice published by the Food and Drug Administration, the Department, or another agency. Where records are retrieved only by personal identifiers other than individual names, a system of records is not a Privacy Act Record System if the Food and Drug Administration cannot, by reference to information under its control, or by reference to records of contractors that are subject to this part under § 21.30, ascertain the identity of individuals who are the subjects of the records.

(d) "Personal identifiers" includes individual names, identifying numbers, symbols, or other identifying designations assigned to individuals. "Personal identifiers" does not include names, numbers, symbols, or other identifying designations that identify products, establishments, or actions.

(e) "Personnel records" means any personal information maintained in a Privacy Act Record System that is needed for personnel management programs or processes such as staffing, employee development, retirement, and grievances and appeals.

(f) "Department" means Department of Health and Human Services.

§ 21.10 Policy concerning records about individuals.

Information about individuals in Food and Drug Administration records shall be collected, maintained, used, and disseminated so as to protect the right to privacy of the individual to the fullest possible extent consistent with laws relating to disclosure of information to the general public, the law enforcement responsibilities of the agency, and administrative and program management needs.

Subpart B—Food and Drug Administration Privacy Act Record Systems

§ 21.20 Procedures for notice of Food and Drug Administration Privacy Act Record Systems.

(a) The Food and Drug Administration shall issue in the FEDERAL REGISTER on or before August 30 of each year a notice concerning each Privacy Act Record System as defined in § 21.3(c) that is not covered by a notice published by the Department, the Office of Personnel Management, or another agency.

(b) The notice shall include the following information:

(1) The name and location(s) of the system.

(2) The categories of individuals about whom records are maintained in the system.

(3) The categories of records maintained in the system.

(4) The authority for the system.

(5) Each routine use of the records contained in the system (i.e., use outside the Department of Health and Human Services that is compatible with the purpose for which the records were collected and described in the notice) including the categories of users and the purposes of such use.

(6) The policies and practices of the Food and Drug Administration regarding storage, retrievability (i.e., how the records are indexed and what intra-agency uses are made of the records), access controls, retention, and disposal of the records in that system.

(7) The title and business address of the official who is responsible for the system of records.

(8) The notification procedure, i.e., the address of the FDA Privacy Act Coordinator, whom any individual can contact to seek notification whether the system contains a record about him/her.

(9) The record access and contest procedures, which shall be the same as the notification procedure except that a reference shall be included to any exemption from access and contest.

(10) Where any records in the system are subject to an exemption under § 21.61, a reference to this exemption.

(11) The categories of sources of records in the system.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981]

§ 21.21 Changes in systems and new systems.

(a) The Food and Drug Administration shall notify the designated Department official, the Office of Management and Budget (Information Systems Division), and the Congress of proposals to change or establish Privacy Act Record Systems in accordance with procedures of the Department and the Office of Management and Budget.

(b) The Food and Drug Administration shall issue a notice, in accordance with paragraph (d) of this section and § 21.20(b), of any change in a Privacy Act Record System which:

(1) Increases the number or types of individuals about whom records are maintained;

(2) Expands the type or amount of information about individuals that is maintained;

(3) Increases the number of categories of agencies or other persons who may have access to those records;

(4) Alters the manner in which the records are organized so as to change the nature or scope of those records, such as the combining of two or more existing systems;

(5) Modifies the way in which the system operates or its location(s) in a manner that alters the process by which individuals can exercise their rights under this part, such as the ways in which they seek access or request amendment of a record; or

(6) Changes the equipment configuration on which the system is operated so as to create the potential for greater access, such as adding a telecommunications capability.

(c) The Food and Drug Administration shall issue a notice of its intention to establish new Privacy Act Record Systems in accordance with paragraph (d) of this section and § 21.20(b).

(d) Notices under paragraphs (b) and (c) of this section shall be published in the FEDERAL REGISTER for comment at least 30 days prior to implementation of the proposed changes or establishment of new systems. Interested persons shall have the opportunity to submit written data, views, or arguments on such proposed new uses or systems.

Subpart C—Requirements for Specific Categories of Records

§ 21.30 Records of contractors.

(a) Systems of records that are required to be operated, or as a matter of practical necessity must be operated, by contractors to accomplish Food and Drug Administration functions, from which information is retrieved by individual names or other personal identifiers, may be subject to the provisions of this part. If the contract is agreed to on or after September 27, 1975, the criminal penalties set forth in 5 U.S.C. 552a(i) are applicable to such contractor, and any employee of such contractor, for disclosures prohibited in § 21.71 or for maintenance of a system of records without notice as required in § 21.20.

(b) A contract is considered to accomplish a Food and Drug Administration function if the proposal or activity it supports is principally operated on behalf of and is under the direct management of the Food and Drug Administration. Systems of records from which information is retrieved by individual names or other personal identifiers and that are operated under contracts to accomplish Food and Drug Administration functions are deemed to be maintained by the agency and shall be subject to the procedures and requirements of this part.

(c) A contract is not considered to accomplish a Food and Drug Administration function if the program or activity it supports is not principally operated on behalf of, or is not under the direct management of, the Food and Drug Administration. For example, this part does not apply to systems of records:

(1) Operated under contract with the Food and Drug Administration by State or local government agencies, or organizations representing such agencies, when such agencies or organizations are also performing State or local government functions.

(2) Operated by contractors with the Food and Drug Administration by individuals or organizations whose primary function is delivery of health services, such as hospitals, physicians, pharmacists, and other health professionals, and that report information concerning products, e.g., injuries or product defects, to the Food and Drug Administration. Before such contractors submit information to the Food and Drug Administration, the names and other personal identifiers of patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted, unless the contract provides otherwise. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(3) Relating to individuals whom the contractor employs, or with whom the contractor otherwise deals, in the course of providing goods and services to the Food and Drug Administration.

(4) Operated under grants.

(d) The requirements of this part shall apply when a contractor who operates a system of records not subject to this part reports to the Food and Drug Administration information that is a system of records about individuals from which personal information is retrieved by names or other personal identifiers. Where the information would be a new Privacy Act Record System, or a change in an existing Privacy Act Record System of a type described in § 21.21, the Food and Drug Administration shall comply with the requirements of § 21.21.

(e) The Food and Drug Administration will review all contracts before award to determine whether operation of a system from which information is retrieved by individual names or other personal identifiers will be required of the contractor, by the terms of the contract or as a matter of practical necessity. If such operation will be required, the solicitation and contract shall include the following clause, or a clause of similar effect:

> Whenever the contractor or any of his employees is required by this contract to operate a system of records from which information is retrieved by individual names or other personal identifiers in order to accomplish a Food and Drug Administration function, the contractor and every employee is considered to be an employee of the Food and Drug Administration and shall operate such system of records in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), regulations of the Food and Drug Administration in 21 CFR Part 21, and rules of conduct that apply to Food and Drug Administration employees who work with such systems of records. The contractor and his employees are subject to the criminal penalties set forth in 5 U.S.C. 552a(i) for violations of the Privacy Act.

§ 21.31 Records stored by the National Archives and Records Administration.

(a) Food and Drug Administration records that are stored, processed, and serviced by the National Archives and Records Administration in accordance with 44 U.S.C. 3103 shall be considered to be maintained by the Food and Drug Administration. The National Archives and Records Administration shall not disclose the record except to authorized Food and Drug Administration employees.

(b) Each Food and Drug Administration record pertaining to an identifiable individual that was transferred to the National Archives of the United States as a record determined by the National Archives to have sufficient historical or other value to warrant its continued preservation shall be considered to be maintained by the National Archives and shall not be subject to the provisions of this part.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985]

§ 21.32 Personnel records.

(a) Present and former Food and Drug Administration employees desiring access to personnel records about themselves should consult system notices applicable to the agency's personnel records that are published by the Office of Personnel Management and the Department as well as any notice issued by the Food and Drug Administration.

(b)(1) The procedures of the Office of Personnel Management at 5 CFR Parts 293, 294, and 297 rather than the procedures in § 21.33 and Subparts D through F of this part, govern systems of personnel records about Food and Drug Administration employees that are subject to notice published by the Office of Personnel Management, i.e., systems that:

(i) The Office of Personnel Management maintains.

(ii) Are maintained by the Division of Human Resources Management, Food and Drug Administration.

(iii) Are maintained by Department Regional Offices, concerning field employees.

(2) The Office of Personnel Management's procedures may, if necessary, be supplemented in the Food and Drug Administration Staff Manual Guide. Current Food and Drug Administration employees should mail or deliver written requests under the Privacy Act for access to personnel records described in this paragraph to the Office of Personnel Management in accordance with 5 CFR 297.106, the Director, Division of Human Resources Management (HFA-400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the personnel officer in the servicing HHS Regional Personnel Office. An employee may consult with or direct his or her request to the FDA Privacy Act Coordinator (HFI-30). Requests for access to personnel records of former employees that are located in Federal

Records Centers should be directed to the Office of Personnel Management. Requests under the Privacy Act for amendment of personnel records should be directed to these same officials who are responsibile for access to personnel records under this paragraph.

(3) With respect to records subject to paragraph (b)(1) of this section:

(i) Refusal to grant access to a record, or refusal to amend a record upon request of an employee, shall only be made by the Associate Commissioner for Management and Operations or his or her designate; and

(ii) Appeals of refusals under paragraph (b)(3)(i) of this section may be made to the Office of Personnel Management in accordance with 5 CFR 297.108(g)(3) and 297.113(b).

(c) Any other Privacy Act Record Systems that contain personnel records, or records that otherwise concern agency employees, that are maintained by offices of the Food and Drug Administration rather than the Division of Human Resources Management but which are not subject to the Department's notice for personnel records in operating offices are subject to this part, except that refusals under this part to grant access to or amend records about present or former employees shall be made by the Associate Commissioner for Management and Operations rather than the Associate Commissioner for Public Affairs.

(d) The following procedures shall govern requests under the Privacy Act for personnel records that are maintained by the operating offices of the Food and Drug Administration in which employees work:

(1) An employee shall upon request be told whether records about him are maintained. An employee shall be given access to records about himself that are subject to this paragraph in response to an oral or written request and through informal procedures, rather than the procedures specified in §§ 21.40 through 21.43.

(2) Employee identity may be verified, if necessary, by an FDA ID card rather than in accordance with § 21.44.

(3) Generally no fee shall be charged for records requested under this paragraph. However, in cases where the records requested are voluminous, a fee may be charged in accordance with § 21.45.

(4) Records that are subject to this paragraph shall be available for access to an individual, except to the extent that access is refused by the Associate Commissioner for Management and Operations or his or her designate on the grounds that the record is subject to an exemption under § 21.61 or 5 CFR 297.111.

(5) Requests under the Privacy Act for amendment of records subject to this paragraph should be directed to the Director, Division of Human Resources Management (HFA-400). Such requests shall be reviewed in accordance with Subpart E of this part. Refusal to amend a record subject to this paragraph (d)(5) shall only be made by the Associate Commissioner for Management and Operations or his or her designate.

(6) Appeals of refusals under paragraph (d)(4) or (5) of this section may be made to the Commissioner of Food and Drugs, except where the Associate Commissioner for Management and Operations or his or her designate indicates with his or her refusal that the appeal should be made to the Office of Personnel Management.

(7) Disclosures of records subject to this paragraph are subject to Subpart G of this part.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

§ 21.33 Medical records.

(a) In general, an individual is entitled to have access to any medical records about himself in Privacy Act Record Systems maintained by the Food and Drug Administration.

(b) The Food and Drug Administration may apply the following special procedures in disclosing medical records to an individual:

(1) The agency may review the records to determine whether disclosure of the record to the individual who is the subject of the records might have an adverse effect on him. If it is determined that disclosure is not likely to have an adverse effect on the individual, the record shall be dis-

closed to him. If it is determined that disclosure is very likely to have an adverse effect on the individual, he may be requested to designate, in writing, a representative to whom the record shall be disclosed. Such representative may be a physician, other health professional, or other responsible person who would be willing to review the record and discuss it with the individual.

(2) The availability of the record may be subject to any procedures for disclosure to an individual of medical records about himself under Part 20 of this chapter, in addition to or in lieu of the procedures in paragraph (b)(1), that are not inconsistent with § 21.41(f).

Subpart D—Procedures for Notification of and Access to Records in Privacy Act Record Systems

§ 21.40 Procedures for submitting requests for notification and access.

(a) An individual may request that the Food and Drug Administration notify him whether a Privacy Act Record System contains records about him that are retrieved by reference to his name or other personal identifier. An individual may at the same time, or after receiving notification that such a record about him exists, requests that he be given access to the record.

(b) An individual desiring notification or access to records shall mail or deliver a request for records in any Food and Drug Administration Privacy Act Records System to the FDA Privacy Act Coordinator (HFI-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Requests shall be in writing and shall name the Privacy Act Record System or Systems concerning which the individual requests notification of whether there are records about him that are retrieved by reference to his name or other personal identifier. To help assure a prompt response, an individual should indicate that he is making a "Privacy Act Request" on the envelope and in a prominent manner in the letter.

(d) An individual who merely wishes to be notified whether a Privacy Act Record System contains a record about him ordinarily need not provide any verification of his identity other than his name. The mere fact that the Food and Drug Administration has a record about an individual in any of its Privacy Act Records Systems would not be likely to constitute a clearly unwarranted invasion of personal privacy. Where mere disclosure of the fact that a record about the individual exists would be a clearly unwarranted invasion of personal privacy, further verification of the identity of the individual shall be required.

(e) An individual who requests that he be given access to a copy of records about himself, if any exist, should indicate whether he prefers (1) to have copies of any such records mailed to him in accordance with § 21.43(a)(1), which may involve a fee under § 21.45, including information to verify his identity under § 21.44 or (2) to use the procedures for access in person under § 21.43(a)(2).

(f) A request for notification and access may be submitted under this subpart concerning any Privacy Act Record System that is exempt under § 21.61, as indicated in the notice for the system. An individual seeking access to records under § 21.65(b)(2) to investigatory records compiled for law enforcement purposes other than criminal law enforcement purposes should submit a description of the right, benefit, or privilege that he believes he was denied as the result of the Food and Drug Administration's maintenance of the records. Where the system is exempt under § 21.61, and access to the requested records is not granted under § 21.65, the request shall be handled under the provisions of Part 20 of this chapter (the public information regulations).

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

§ 21.41 Processing of requests.

(a) An individual or his guardian under § 21.75 shall not be required to show any justification or need to obtain notification under § 21.42 or access to a record under § 21.43.

(b) The Food and Drug Administration will determine whether a request by an individual for records about himself is appropriately treated as a request under this subpart, or under the provision of Part 20 of this chapter (the public information regulations), or both. Where appropriate, the Food and Drug Administration will consult with the individual concerning the appropriate treatment of the request.

(c) The FDA Privacy Act Coordinator (HFI-30) in the Freedom of Information Staff shall be responsibile for the handling of Privacy Act requests received by the Food and Drug Administration. Requests mailed or delivered to any other office shall be promptly redirected to the FDA Privacy Act Coordinator. Where this procedure would unduly delay the agency's response, however, the agency employee who received the request should consult with the FDA Privacy Act Coordinator and obtain advice as to whether the employee can respond to the request directly.

(d) Upon receipt of a request by the FDA Privacy Act Coordinator, a record shall promptly be made that a request has been received and the date.

(e) A letter in accordance with § 21.42 responding to the request for notification shall issue as promptly as possible after receipt of the request by the Food and Drug Administration. Upon determination by the Freedom of Information Staff that a request for access to records is appropriately treated as a request under Part 20 of this chapter rather than Part 21, or under both parts, the time limitations prescribed in § 21.41 shall apply. In any case, access to available records shall be provided as promptly as possible.

(f) Except as provided in § 21.32, an individual's access to records about him/herself that are retrieved by his/her name or other personal identifiers and contained in any Privacy Act Record System may only be denied by the Associate Commissioner for Public Affairs or his or her designate. An individual shall not be denied access to any record that is otherwise available to him/her under this part except on the grounds that it is exempt under § 21.65(a)(2), that it was compiled in reasonable anticipation of court litigation of formal administrative proceedings, or to the extent that it is exempt or prohibited from disclosure because it includes a trade secret or commercial or financial information that is privileged or confidential information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy of another individual.

(g) The FDA Privacy Act Coordinator shall ensure that records are maintained of the number, status, and disposition of requests under this subpart, including the number of requests for records exempt from access under this subpart and other information required for purposes of the annual report to Congress under the Privacy Act. These temporary administrative management records shall not be considered to be Privacy Act Record Systems. All records required to be kept under this paragraph shall only include requesting individuals' names or personal identifiers for so long as any request for notification, access, or amendment is pending. The identity of individuals making request under this subpart shall be regarded as confidential and shall not be disclosed under Part 20 of this chapter (the public information regulations) to any other person or agency except as is necessary for the processing of requests under this subpart.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981]

§ 21.42 Responses to requests.

(a) The FDA shall respond to an individual's request for notification as to whether a Privacy Act Record System contains records about him that are retrieved by his name or other personal identifier by sending a letter under this paragraph.

(1) If there are no records about the individual that are retrieved by his name or other personal identifier in the named Privacy Act Record System, or the requester is not an "individual" under § 21.3(a), the letter shall so state. Where appropriate, the letter shall indicate that the Food and Drug Administration's public informa-

tion regulations in Part 20 of this chapter prescribe general rules governing the availability of information to members of the public, and that a request may be made in accordance with Part 20 of this chapter for records that are not retrieved by the requester's name or other personal identifier from a Privacy Act Record System.

(2) If there are records about the individual that are retrieved by his name or other personal identifier and the named Privacy Act Record System is not exempt from individual access and contest under § 21.61, or the system is exempt but access is allowed or required under § 21.65, the letter shall inform him that the records exist and shall either:

(i) Enclose a copy of the records under § 21.43(a)(1) or indicate that the records will be sent under separate cover, where there has been adequate verification of the identity of the individual under § 21.44 and the fees under § 21.45 do not exceed $25, or

(ii) Inform the individual of the procedures to obtain access to the records by mail or in person under § 21.43(a)(2), as well as the approximate dates by which the requested records can be provided (if the records are not then available), the locations at which access in person may be had, and the information needed, if any, to verify the identity of the individual under § 21.44.

(3) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, and the system is exempt from individual access and contest under § 21.61 and access is not allowed or required under § 21.65, the letter should inform him that the records are exempted from access and contest by § 21.61. The letter shall also inform him if the records sought are not available because they were compiled in reasonable anticipation of court litigation or formal administrative proceedings or are otherwise not available under § 21.41(b). Where appropriate, the letter shall also indicate whether the records are available under Part 20 of this chapter (the public information regulations), and it may disclose the records in accordance with Part 20.

(4) If the named Privacy Act Record System contains records about the individual that are retrieved by his name or other personal identifier, but a final determination has not yet been made with respect to disclosure of all of the records covered by the request, e.g., because it is necessary to consult another person or agency having an interest in the confidentiality of the records, the letter shall explain the circumstances and indicate when a final answer will be given.

(b) Except as provided in § 21.32, access to a record may only be denied by the Associate Commissioner for Public Affairs or his or her designate. If access to any record is denied wholly or in substantial part, the letter shall state the right of the individual to appeal to the Commissioner of Food and Drugs.

(c) If a request for a copy of the records will result in a fee of more than $25, the letter shall specify or estimate the fee involved. Where the individual has requested a copy of any records about him and copying the records would result in a fee of over $50, the Food and Drug Administration shall require advance deposit as well as payment of any amount not yet received as a result of any previous request by the individual for a record about himself, under this subpart or Part 20 of this chapter (the public information regulations) before the records are made available. If the fee is less than $50, prepayment shall not be required unless payment has not yet been received for records disclosed as a result of a previous request by the individual for a record about himself under this subpart or Part 20 of this chapter.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981]

§ 21.43 Access to requested records.

(a) Access may be granted to requested records by:

(1) Mailing a copy of the records to the requesting individual, or

(2) Permitting the requesting individual to review the records in person between 9 a.m. and 4 p.m. at the office

of the FDA Privacy Act Coordinator, at the Freedom of Information Staff Public Room at the address shown in § 20.30 of this chapter, or at any Food and Drug Administration field office listed in § 5.115 of this chapter or at another location or time upon which the Food and Drug Administration and the individual agree. Arrangement for such review can be made by consultation between the FDA Privacy Act Coordinator and the individual. An individual seeking to review records in person shall generally be permitted access to the file copy, except that where the records include nondisclosable information, a copy shall be made of that portion of the records, with the nondisclosable information blocked out. Where the individual is not given a copy of the record to retain, no charge shall be made for the cost of copying a record to make it available to an individual who reviews a record in person under this paragraph.

(b) An individual may request that a record be disclosed to or discussed in the presence of another individual, such as an attorney. The individual may be required to furnish a written statement authorizing the disclosure or discussion in such other individual's presence.

(c) The Food and Drug Administration will make every reasonable effort to assure that records made available under this section can be understood by the individual, such as by providing an oral or written explanation of the records.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981]

§ 21.44 Verification of identity.

(a) An individual seeking access to records in a Privacy Act Record System may be required to comply with reasonable requirements to enable the Food and Drug Administration to determine his identity. The identification required shall be suitable considering the nature of the records sought. No identification shall be required to receive access to information that is required to be disclosed to any member of the public under Part 20 of this chapter (the public information regulations).

(b) An individual who appears in person for access to records about himself shall be required to provide at least one document to identify himself, e.g., driver's license, passport, or alien or voter registration card to verify his identity. If an individual does not have any such document or requests access to records about himself without appearing in person under circumstances in which his identity cannot be verified from the request itself, he shall be required to certify in writing that he is the individual he claims to be and that he understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a $5,000 fine.

(c) In making requests under § 21.75, a parent of a minor child or legal guardian of an incompetent individual may be required to verify his relationship to the minor child or the incompetent individual, in addition to verifying his own identity, by providing a copy of the minor's birth certificate, a court order, or other evidence of guardianship.

(d) Where an individual seeks access to particularly sensitive records, such as medical records, the individual may be required to provide additional information beyond that specified in paragraph (b) or (c) of this section, such as the individual's years of attendance at a particular educational institution, rank attained in the uniformed services, date or place of birth, names of parents, an occupation, or the specific times the individual received medical treatment.

§ 21.45 Fees.

(a) Where applicable, fees for copying records shall be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual has requested that a copy be made of a record to which he is granted access. No fee may be charged for making a search of a Privacy Act Record System whether the search is manual, mechanical, or electronic. Where a copy of the record must be made to provide access to the record, e.g., computer printout where no screen reading is available, the copy shall be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual under § 21.33, no fee will be charged.

(b) The fee schedule is as follows:

(1) Copying of records susceptible to photocopying—$.10 per page.

(2) Copying of records not susceptible to photocopying, e.g., punch cards or magnetic tapes—at actual cost to the determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying for an individual does not exceed $25.

(c) When a fee is to be assessed, the individual shall be notified prior to the processing of the copies, and be given an opportunity to amend his request. Payment shall be made by check or money order made payable to the "Food and Drug Administration," and shall be sent to the Accounting Branch (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Advance deposit shall be required where the total amount exceeds $50.

[42 FR 15626, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989]

Subpart E—Procedures for Requests for Amendment of Records

§ 21.50 Procedures for submitting requests for amendment of records.

(a) An individual who received access to a record about himself under Subpart D of this part may request that the record be amended if he believes that the record or an item of information is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete.

(b) Amendments under this subpart shall not violate existing statute, regulation, or administrative procedure.

(1) This subpart does not permit alteration of evidence presented in the course of judicial proceedings or Food and Drug Administration adjudicatory or rule making proceedings or collateral attack upon that which has already been the subject of any such proceedings.

(2) If the accuracy, relevancy, timeliness, or completeness of the records may be contested in any other pending or imminent agency proceeding, the Food and Drug Administration may refer the individual to the other proceeding as the appropriate means to obtain relief. If the accuracy, relevance, timeliness, or completeness of a record is, or has been, an issue in another agency proceeding, the request under this section shall be disposed of in accordance with the decision in the other proceeding, absent unusual circumstances.

(c) Requests to amend records shall be submitted, in writing, to the FDA Privacy Act Coordinator in accordance with § 21.40(b). Such requests shall include information sufficient to enable the Food and Drug Administration to locate the record, a brief description of the items of information requested to be amended, and the reasons why the record should be amended together with any appropriate documentation or arguments in support of the requested amendment. An edited copy of the record showing the described amendment may be included. Verification of identity should be provided in accordance with § 21.44.

(d) Written acknowledgement of the receipt of a request to amend a record shall be provided within 10 working days to the individual who requested the amendment. Such acknowledgement may request any additional information needed to verify identity or make a determination. No acknowledgement need be made if the request can be reviewed, processed, and the individual notified of the agency's agreement with the request or refusal within the 10-day period.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981]

§ 21.51 Responses to requests for amendment of records.

(a) The Food and Drug Administration shall take one of the following actions on a request for amendment of records as promptly as possible:

(1) Amend any portion of the record which the agency has determined, based upon a preponderance of the evidence, is not accurate, relevant to a Food and Drug Administration purpose, timely, or complete, and, in ac-

cordance with paragraph (d)(3) of this section, inform the individual and previous recipients of the record that has been amended of the amendment.

(2) Inform the individual of its refusal to amend any portion of the record in the manner requested, the reason for the refusal, and the opportunity for administrative appeal to the Commissioner of Food and Drugs. Except as provided in § 21.32, such refusal may only be issued by the Associate Commissioner for Public Affairs or his or her designate.

(3) Where another agency was the source of and has control of the record, refer the request to that agency.

(b) The agency may, for good cause, extend the period for taking action an additional 30 working days if notice is provided to the individual explaining the circumstances of the delay.

(c) The officials charged with reviewing a record to determine how to respond to a request to amend it, shall assess its accuracy, relevance to a Food and Drug Administration purpose, timeliness, or completeness. The determination shall be made in the light of the purpose for which the records or system is used, the agency's need for the record, and the possible adverse consequences to the individual from the record if not amended. Whenever the Food and Drug Administration receives a request for deletion of a record, or portions of a record, it shall consider anew whether the contested information in the record is relevant and necessary to a Food and Drug Administration purpose.

(d) If the Food and Drug Administration agrees with an individual's request, it shall take the following actions:

(1) So inform the individual in writing.

(2) In accordance with statute, regulation, or procedure, amend the record to make it accurate, relevant to a Food and Drug Administration purpose, timely, or complete, making note of the date and fact of the amendment.

(3) If an accounting was made under § 21.71(d) of a disclosure of the record under § 21.71(a), provide a copy of the record as amended, to all previous recipients of the record.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981]

§ 21.52 Administrative appeals of refusals to amend records.

(a) If an individual disagrees with a refusal under § 21.51(a)(2) to amend a record, he or she may appeal that refusal to the Commissioner of Food and Drugs, Rm. 14-71, 5600 Fishers Lane, Rockville, MD 20857.

(b) If, upon appeal, the Commissioner upholds the refusal to amend the record as requested, he shall inform the individual:

(1) Of his decision and the reasons for it.

(2) Of the individual's right to file with the Food and Drug Administration a concise statement of the individual's reasons for disagreeing with the agency's decision not to amend the record as requested.

(3) That the statement of disagreement will be made available to all persons listed in an accounting as having previously received the record and any person to whom the record is subsequently disclosed together with, in the discretion of the Food and Drug Administration, a brief statement summarizing its reasons for refusing to amend the record. Any individual who includes false information in the statement of disagreement filed with the Food and Drug Administration may be subject to penalties under 18 U.S.C. 1001, the False Reports to the Government Act.

(4) That the individual has a right to seek judicial review of the refusal to amend the record.

(c) If the Commissioner on administrative appeal or a court on judicial review determines that the record should be amended in accordance with the individual's request, the Food and Drug Administration shall proceed in accordance with § 21.51(d).

(d) A final determination on the individual's administrative appeal of the initial refusal to amend the record shall be concluded within 30 working days of the request for such review under paragraph (a) of this section, unless the Commissioner extends such period for good cause and informs the individual in writing of the reasons for the delay and of the approximate date on which a decision of the appeal can be expected.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985]

§ 21.53 Notation and disclosure of disputed records.

When an individual has filed a statement of disagreement under § 21.52(b)(2), the Food and Drug Administration shall:

(a) Mark any portion of the record that is disputed to assure that the record will clearly show that portion is disputed whenever the record is disclosed.

(b) In any subsequent disclosure under § 21.70 or § 21.71(a), provide a copy of the statement of disagreement and, if the Food and Drug Administration deems it appropriate, a concise statement of the agency's reasons for not making the amendment(s) requested. While the individual shall have access to any such statement, it shall not be subject to a request for amendment under § 21.50.

(c) If an accounting was made under § 21.71(d) and (e) of a disclosure of the record under § 21.71(a), provide to all previous recipients of the record a copy of the statement of disagreement and the agency statement, if any.

§ 21.54 Amended or disputed records received from other agencies.

Whenever the Food and Drug Administration is notified that a record that it received from another agency was amended or is the subject of a statement of disagreement, the Food and Drug Administration shall:

(a) Discard the record, or clearly note the amendment or the fact of disagreement in its copy of the record, and

(b) Refer persons who subsequently request the record to the agency that provided it.

(c) If an accounting was made under § 21.71 (d) and (e) of the disclosure of the record under § 21.71(a), inform all previous recipients of the record about the amendment or provide to them the statement of disagreement and the agency statement, if any.

Subpart F—Exemptions

§ 21.60 Policy.

It is the policy of the Food and Drug Administration that record systems should be exempted from the Privacy Act only to the extent essential to the performance of law enforcement functions under the laws that are administered and enforced by the Food and Drug Administration or that govern the agency.

§ 21.61 Exempt systems.

(a) Investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, in the Food and Drug Administration Privacy Act Record Systems listed in paragraph (b) of this section are exempt from the following provisions of the Privacy Act (5 U.S.C. 552a) and of this part:

(1) Such records are exempt from 5 U.S.C. 552a(c)(3) and § 21.71(e)(4), requiring that an individual be provided with the accounting of disclosures of records about himself from a Privacy Act Record System.

(2) Except where access is required under 5 U.S.C. 552a(k)(2) and § 21.65(a)(2), (such records are exempt from 5 U.S.C. 552a(d)(1) through (4) and (f)) and §§ 21.40 through 21.54, requiring procedures for an individual to be given notification of and access to records about himself in a Privacy Act Record System and to be allowed to challenge the accuracy, relevance, timeliness, and completeness of such records.

(3) Such records are exempt from 5 U.S.C. 552a(e)(4)(G) and (H) and § 21.20(b)(1) requiring inclusion in the notice for the system of information about agency procedures for notification, access, and contest.

(4) Such records are exempt from 5 U.S.C. 552a(e)(3) requiring that individuals asked to supply information be provided a form outlining the authority for the request, the purposes for which the information will be used, the routine uses in the notice for the Privacy Act Record System, and the consequences to the individual of not providing the information, but only with respect to records compiled by

the Food and Drug Administration in a criminal law enforcement investigation where the conduct of the investigation would be prejudiced by such procedures.

(b) Records in the following Food and Drug Administration Privacy Act Record Systems that concern individuals who are subject to Food and Drug Administration enforcement action and consist of investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, are exempt under 5 U.S.C. 552a(j)(2) and (k)(2) from the provisions enumerated in paragraph (a) of this section:

(1) Bio-research Monitoring Information System—HHS/FDA/09-10-0010.

(2) Regulated Industry Employee Enforcement Records—HHS/FDA/ACMO/09-10-002.

(3) Employee Conduct Investigative Records—HHS/FDA/ACMO/09-10-0013.

(c) The system described in paragraph (b)(3) of this section includes investigatory records compiled solely for the purpose of determining suitability, eligibility, or qualification for Federal civilian employment, military service, Federal contracts, and access to classified information. These records are exempt from disclosure under 5 U.S.C. 552a(k)(5) to the extent that the disclosure would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished after September 27, 1975. Any individual who is refused access to a record that would reveal a confidential source shall be advised in a general way that the record includes information that would reveal a confidential source.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

§ 21.65 Access to records in exempt systems.

(a) Where a Privacy Act Record System is exempt and the requested records are unavailable under § 21.61, an individual may nevertheless make a request under § 21.40 for notification concerning whether any records about him exist and request access to such records where they are retrieved by his name or other personal identifier.

(b) An individual making a request under paragraph (a) of this section;

(1) May be given access to the records where available under Part 20 of this chapter (the public information regulations) or the Commissioner may, in his discretion, entertain a request under any or all of the provisions of §§ 21.40 through 21.54; and

(2) Shall be given access upon request if the records requested are subject to 5 U.S.C. 552a(k)(2) and not to 5 U.S.C. 552a(j)(2) (i.e., because they consist of investigatory material compiled for law enforcement purposes other than criminal law enforcement purposes) and maintenance of the records resulted in denial to the individual of any right, benefit, or privilege to which he would otherwise be entitled by Federal law, or for which he would otherwise be eligible. An individual given access to a record under this paragraph (b)(2) is not entitled to seek amendment under Subpart E of this part. The FDA may refuse to disclose a record that would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished on or after September 27, 1975. Any individual refused access to a record that would reveal a confidential source shall be advised in a general way that the record contains information that would reveal a confidential source.

(c) The Commissioner shall not make available any record that is prohibited from public disclosure under § 20.82(b) of this chapter.

(d) Discretionary disclosure of a record pursuant to paragraph (b)(1) of this section shall not set a precedent for discretionary disclosure of a similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record in a system that is exempt under § 21.61.

Subpart G—Disclosure of Records in Privacy Act Record Systems to Persons Other Than the Subject Individual

§ 21.70 Disclosure and intra-agency use of records in Privacy Act Record Systems; no accounting required.

(a) A record about an individual which is contained in a Privacy Act Record System may be disclosed:

(1) To the individual who is the subject of the record, or his legal guardian under § 21.75;

(2) To a third party pursuant to a written request by, or within a written consent of, the individual to whom the record pertains, or his legal guardian under § 21.75;

(3) To any person:

(i) Where the names and other identifying information are first deleted, and under circumstances in which the recipient is unlikely to know the identity of the subject of the record;

(ii) Where disclosure is required by Part 20 of this chapter (the public information regulations); or

(4) Within the Department of Health and Human Services to officers and employees who have a need for the record in the performance of their duties in connection with the laws administered and enforced by the Food and Drug Administration or that govern the agency. For purposes of this section, officers or employees of the Department shall include the following categories of individuals, who shall thereafter be subject to the same restrictions with respect to disclosure as any Food and Drug Administration employee: Food and Drug Administration consultants and advisory committees, State and local government employees for use only in their work with the Food and Drug Administration, and contractors and their employees to the extent that the records of such contractors are subject to the requirements of this part under § 21.30.

(b) No accounting is required for any disclosure or use under paragraph (a) of this section.

§ 21.71 Disclosure of records in Privacy Act Record Systems; accounting required.

(a) Except as provided in § 21.70, a record about an individual that is contained in a Privacy Act Record System shall not be disclosed by any method of communication except under any of the following circumstances, which are subject to the limitations of paragraphs (b) and (c) of this section and to the accounting requirement of paragraph (d) of this section:

(1) To those officers and employees of the agency which maintains the record who have a need for the record in the perfomance of their duties;

(2) Required under section 552 of the Freedom of Information Act;

(3) For a routine use as described in the routine use section of each specific system notice;

(4) To the Bureau of Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of Title 13 of the U.S. Code;

(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and that the record is to be transferred in a form that is not individually identifiable;

(6) To the National Archives and Records Administration of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the U.S. Government, or to the Archivist of the United States or his or her designee for evaluation to determine whether the record has such value;

(7) To another agency or to an instrumentality of any government jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an indi-

vidual if, upon such disclosure, notification is transmitted to the last known address of such individual;

(9) To either House of Congress or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

(10) To the Comptroller General, or any of his or her authorized representatives in the course of the performance of the duties of the General Accounting Office;

(11) Pursuant to the order of a court of competent jurisdiction; or

(12) To a consumer reporting agency in accordance with section 3(d) of the Federal Claims Collection Act of 1966 (31 U.S.C. 952(d)). (This "Special Disclosure" statement does not apply to any FDA system of records.)

(b) The Food and Drug Administration may in its discretion refuse to make a disclosure permitted under paragraph (a) of this section, if the disclosure would in the judgment of the agency, invade the privacy of the individual or be inconsistent with the purpose for which the information was collected.

(c) The Food and Drug Administration may require any person requesting a disclosure of a record under paragraph (a) of this section to provide:

(1) Information about the purposes to which the disclosed record is to be put, and

(2) A written statement certifying that the record will be used only for the stated purposes and will not be further disclosed without the written permission of the Food and Drug Administration.

Under 5 U.S.C. 552a(i)(3), any person who knowingly or willfully requests or obtains any record concerning an individual from an agency under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000. Such person may also be subject to prosecution under the False Reports to the Government Act, 18 U.S.C. 1001.

(d) An accounting shall be made, in accordance with paragraph (e) of this section, of any disclosure under paragraph (a) of this section of a record that is not a disclosure under § 21.70.

(e) Where an accounting is required under paragraph (d) of this section, the Food and Drug Administration shall:

(1) Record the name and address of the person or agency to whom the disclosure is made and the date, nature, and purpose of the disclosure. The accounting shall not be considered a Privacy Act Record System.

(2) Retain the accounting for 5 years or for the life of the record, whichever is longer, following the disclosure.

(3) Notify those recipients listed in the accounting of amendments or disputes concerning the records previously disclosed to them pursuant to §§ 21.51(d)(3), 21.53(c), or 21.54(c).

(4) Except when the record is exempt from individual access and contest under § 21.61 or to the extent that the accounting describes a transfer for a law enforcement purpose pursuant to paragraph (a)(7) of this section, make the accounting available to the individual to whom the record pertains, in accordance with procedures of Subpart D of this part.

(f) A single accounting may be used to cover disclosure(s) that consist of a continuing dialogue between two agencies over a prolonged period, such as discussion of an enforcement action between the Food and Drug Administration and the Department of Justice. In such cases, a general notation may be made that, as of a certain date, contract was initiated, to continue until resolution of the matter.

[42 FR 15626, Mar. 22, 1977, as amended at 50 FR 52278, Dec. 23, 1985; 54 FR 9038, Mar. 3, 1989]

§ 21.72 Individual consent to disclosure of records to other persons.

(a) Individuals may consent to disclosure of records about themselves to other persons in several ways, for example:

(1) An individual may give consent at the time that the information is collected for disclosure for specific purposes or to specific persons.

(2) An individual may give consent for disclosure of his records to a specific person.

(3) An individual may request the Food and Drug Administration to transcribe a specific record for submission to another person.

(b) In each case the consent shall be in writing and shall specify the individual, organizational unit, or class of individuals or organizational units to whom the record may be disclosed, which record may be disclosed, and, if applicable, for what time period. A blanket consent to release all of an individual's records to unspecified individuals or organizational units will not be honored. Verification of the identity of the individual and, where applicable, of the person to whom the record is to be disclosed shall be made in accordance with § 21.44. Consent documents shall be retained for a period of at least 2 years. If such documents are used as a means of accounting for the disclosure, they shall be retained as provided in § 21.71(e)(2).

§ 21.73 Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.

(a) The Food and Drug Administration shall make reasonable efforts to assure that a record about an individual in a Privacy Act Record System is accurate, relevant to a Food and Drug Administration purpose, timely, and complete before such record is disclosed under § 21.71.

(b) Paragraph (a) of this section shall not apply to disclosures that are required under Part 20 of this chapter (the public information regulations) or made to other Federal Government departments and agencies. Where appropriate, the letter disclosing the information shall indicate that the Food and Drug Administration has not reviewed the record to assure that it is accurate, relevant, timely, and complete.

§ 21.74 Providing notice that a record is disputed.

Whenever an individual has filed a statement of disagreement with the Food and Drug Administration concerning a refusal to amend a record under § 21.51(a)(2) or with another agency that provides the record to the Food and Drug Administration, the Food and Drug Administration shall in any subsequent disclosure under this subpart provide a copy of the statement of disagreement and a concise statement by the agency, if one has been prepared, of the reasons for not making the amendment(s) requested.

§ 21.75 Rights of legal guardians.

For the purposes of this part, the parent of any individual who is a minor or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction may act on behalf of the individual.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

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Sec.
25.31d Environmental assessment for establishment of tolerances or action levels—Format 4.
25.31e Environmental assessment for destruction of condemned, enjoined, detained, or recalled articles—Format 5.
25.32 Finding of no significant impact.
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Subpart D—Agency Decisionmaking

25.40 Procedures for incorporating environmental considerations into agency decisionmaking.
25.41 Actions for which a finding of no significant impact and an environmental assessment are prepared.
25.42 Actions for which an environmental impact statement is prepared.

Subpart E—Other Requirements

25.50 Environmental effects abroad of major agency actions.

AUTHORITY: Sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371); secs. 351, 354-361, 58 Stat. 702 as amended (42 U.S.C. 262, 263b-264); sec. 102(2)(C), 83 Stat. 853 (42 U.S.C. 4332); 40 CFR Parts 1500–1508; Executive Order 11514 as amended by E.O. 11991; E.O. 12114.

SOURCE: 50 FR 16656, Apr. 26, 1985, unless otherwise noted.

Subpart A—General Provisions

§ 25.1 Purpose.

(a) The Food and Drug Administration (FDA) recognizes the National Environmental Policy Act of 1969 (NEPA) as the national charter for protection, restoration, and enhancement of the environment. NEPA establishes policy, sets goals (section 101), and provides procedures (section 102) for carrying out the policy. This part supplements the regulations for implementing the procedural provisions of NEPA which were published by the Council on Environmental Quality (CEQ) in 40 CFR Parts 1500-1508 and the procedures included in the HHS General Administration Manual, Part 30: Environmental Protection (45 FR 76519-76534, Nov. 19, 1980).

(b) These supplemental procedures provide that: (1) Environmental information is to be available to the public and the decisionmaker before decisions are made about actions that may significantly affect the quality of the human environment; (2) FDA actions are to be supported by accurate scientific analyses; and (3) environmental documents are to concentrate on timely and significant issues, not to amass needless detail.

(c) These supplemental procedures for implementing NEPA allow FDA to assist individuals and non-Federal public entities in choosing courses of action that protect and enhance environmental quality.

(d) To avoid delays in decisionmaking, these supplemental procedures make possible the early identification of actions that may significantly affect the quality of the human environment.

(e) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 25.5 Policies.

(a) All FDA policies and programs will be planned, developed, and implemented so as to achieve the policies declared by NEPA and required by the CEQ regulations to ensure responsible stewardship of the environment for present and future generations.

(b) If a proposed action for which an EIS will be prepared involves possible environmental effects that are required to be considered under statutes or Executive Orders other than those referred to under "AUTHORITY" in this part, these effects shall be considered in the NEPA review, consistent with 40 CFR 1502.25 and the HHS General Administration Manual, Part 30: Environmental Protection.

(c) Part 30 of the HHS General Administration Manual addresses the following statutes, Executive Orders, and other authorities not referred to under "AUTHORITY" in this part:

(1) *The Coastal Zone Management Act,* 16 U.S.C. 1456 et seq., directs Federal agencies to conduct activities consistent with an approved State coastal zone management program.

(2) *The Wild and Scenic Rivers Act,* 16 U.S.C. 1278, directs Federal agencies to consider and preserve the values of wild and scenic areas in the

use and development of water and land resources.

(3) *Executive Order 11990*, May 24, 1977, directs heads of Federal agencies to avoid the long- and short-term adverse impacts associated with the destruction or modification of wetlands and direct or indirect support of new construction in wetlands whenever there is a practical alternative.

(4) *Executive Order 11988*, May 24, 1977, directs Federal agencies to take action to avoid the occupancy or modification of floodplains and to avoid direct or indirect support of development in floodplain areas whenever there is a practical alternative.

(5) *U.S. Water Resources Council Floodplain Management Guidelines*, February 10, 1978, provides guidance to Federal agencies for implementing E.O. 11988.

(6) *Marine Protection, Research and Sanctuaries Act*, 33 U.S.C. 1432f, provides for establishment of marine sanctuaries and directs Federal agencies to ensure that their actions are consistent with the intended use of such areas.

(7) *The Safe Drinking Water Act*, 42 U.S.C. 300f, et seq., authorizes EPA to determine if an action which will have an environmental effect on a sole or principal drinking water source would also constitute a significant hazard to a human population and, if so, to prohibit such an action.

(8) *The Clean Air Act*, 42 U.S.C. 1875h-7, requires EPA to review and comment on a Federal agency action which would create a significant environmental impact.

(9) *Executive Order 11987*, May 24, 1977, directs Federal agencies to prevent the introduction of exotic species into the natural ecosystems of the United States.

(10) *The Endangered Species Act*, 16 U.S.C. 1536, directs Federal agencies to conserve endangered and threatened species and their critical habitats.

(11) *Fish and Wildlife Coordination Act*, 16 U.S.C. 661-666c, directs Federal agencies to prevent loss and damage to, and provide for, development and improvement of wildlife resources.

(12) *The National Historic Preservation Act of 1966*, 16 U.S.C. 470 as amended, directs heads of Federal agencies to preserve cultural heritage, particularly with respect to sites on/or eligible for listing on the National Register of Historic Places.

(13) *Executive Order 11593*, May 5, 1971, implements portions of the National Historical Preservation Act of 1966 and requires the Federal government to nominate eligible properties which it owns, leases, or otherwise controls.

(14) *Regulations of the Advisory Council on Historic Preservation* (36 CFR Part 800) establish procedures for the protection of historic and cultural properties.

(15) *Regulations of the Department of the Interior* (36 CFR Parts 60 and 63) concern nominations to and determinations of eligibility for the National Register of Historic Places.

(16) *The Archaeological and Historic Preservation Act*, 16 U.S.C. 469a-1, et seq., directs Federal agencies to preserve significant scientific, prehistorical, historical, and archaeological data.

§ 25.10 NEPA planning.

(a) Environmental impact consideration is an integral part of FDA's regulatory process. For actions initiated by the agency, the process begins when FDA identifies a problem that requires action by the agency under the statutes it administers. For actions initiated by applicants or petitioners, the process begins when FDA receives from an applicant or petitioner an environmental assessment (EA) or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions. FDA also may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potentially significant environmental impacts. Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time. FDA's assessment of environmental factors includes the identification of the parts of the environment that may be affected by the action, the evaluation of pertinent environmental data, and the consideration of alternatives consistent with 40 CFR 1502.14.

(b) FDA will be the lead agency for actions under programs it administers. As lead agency, FDA will coordinate the participation of all concerned agencies in developing an environmental impact statement (EIS) according to 40 CFR 1501.6(a). If an action affects more than one center within FDA, the Commissioner of Food and Drugs will designate one of these units to be responsible for coordinating the preparation of any required environmental documentation.

(c) FDA and other affected Federal agencies will agree which one will be the lead agency and which will be the cooperating agencies for actions under programs not administered by FDA. If an agreement cannot be reached, the procedures in 40 CFR 1501.5(e) will be followed.

(d) FDA will act as a cooperating agency if requested. FDA may request to be designated as a cooperating agency if proposed actions may affect areas of FDA responsibility. As a cooperating agency, FDA will comply with the procedures in 40 CFR 1501.6(b) to the extent possible depending on priority and the availability of funds and personnel.

§ 25.15 Terminology.

(a) Definitions that apply to the terms used in this part are set forth in the CEQ regulations under 40 CFR Part 1508. The terms and the sections of 40 CFR Part 1508 in which they are defined follow:

(1) Categorical exclusion (40 CFR 1508.4).

(2) Cooperating Agency (40 CFR 1508.5).

(3) Cumulative impact (40 CFR 1508.7).

(4) Effects (40 CFR 1508.8).

(5) Environmental Assessment (EA) (40 CFR 1508.9).

(6) Environmental document (40 CFR 1508.10).

(7) Environmental Impact Statement (EIS) (40 CFR 1508.11).

(8) Federal Agency (40 CFR 1508.12).

(9) Finding of No Significant Impact (FONSI) (40 CFR 1508.13).

(10) Human environment (40 CFR 1508.14).

(11) Lead Agency (40 CFR 1508.16).

(12) Legislation (40 CFR 1508.17).

(13) Major Federal Action (40 CFR 1508.18).

(14) Mitigation (40 CFR 1508.20).

(15) NEPA Process (40 CFR 1508.21).

(16) Notice of Intent (40 CFR 1508.22).

(17) Proposal (40 CFR 1508.23).

(18) Scope (40 CFR 1508.25).

(19) Significantly (40 CFR 1508.27).

(b) The following terms are defined solely for the purpose of implementing the supplemental procedures provided by this part and are not necessarily applicable to any other statutory or regulatory requirements:

(1) "Agency" means the Food and Drug Administration (FDA).

(2) "Emissions requirements" specifies the limits on the quantities of pollutants allowed to be released into the work place and the area outside a production site or facility. These requirements or standards are set and enforced by local, State, and Federal government components, e.g., Environmental Protection Agency, Occupational Safety and Health Administration.

(3) "Environmental assessment technical guide" means that technical guidance prepared by FDA and intended to assist applicants and petitioners in preparing their environmental assessments.

(4) "Production" includes manufacture, processing, and packaging operations for FDA-regulated articles that are the subject of proposed actions.

(5) "Responsible agency official" means the agency decisionmaker designated in Part 5 of this chapter, the Commissioner of Food and Drugs, or the Commissioner's designated representative.

(6) "Toxic substance" means any substance that is harmful to some biological mechanism or system. Although it is recognized that any substance may produce damage to biological mechanisms or systems under specific conditions, for the purpose of these regulations, a substance is considered to be a toxic substance if it is

harmful to appropriate test organisms at expected environmental concentrations even though it may be without effect to humans or other organisms at these concentrations and may even be used by humans because of its toxic properties. A substance is considered toxic in the environment if the maximum concentration of the substance at any point in the environment, i.e., either at any point of entry or any point where higher concentrations are expected as a result of bioaccumulation or other types of concentration processes, exceeds the concentration of the substance that causes any adverse effect in a test organism species (minimum effect level) or exceeds 1/100 of the concentration that causes 50-percent mortality in a test organism species, whichever concentration is less.

(c) The following acronyms are used in this part:

(1) ANDA—Abbreviated New Drug Application.

(2) CAS—Chemical Abstracts Service.

(3) CEQ—Council on Environmental Quality.

(4) CFR—Code of Federal Regulations.

(5) CGMP—Current Good Manufacturing Practice.

(6) EA—Environmental Assessment.

(7) EIS—Environmental Impact Statement.

(8) EPA—Environmental Protection Agency.

(9) FDA—Food and Drug Administration.

(10) FFD&C Act—Federal Food, Drug, and Cosmetic Act.

(11) FIFRA—Federal Insecticide, Fungicide and Rodenticide Act.

(12) FONSI—Finding of No Significant Impact.

(13) GLP—Good Laboratory Practice.

(14) GRAS—Generally Recognized as Safe.

(15) HHS—Department of Health and Human Services.

(16) IDE—Investigational Device Exemption.

(17) INAD—Notice of Claimed Investigational Exemption for New Animal Drug.

(18) IND—Investigational New Drug Application.

(19) NADA—New Animal Drug Application.

(20) NDA—New Drug Application.

(21) NEPA—National Environmental Policy Act of 1969.

(22) OTC—Over-the-Counter.

(23) PMA—Premarket Approval Application.

(24) PDP—Product Development Protocol.

(25) TSCA—Toxic Substances Control Act.

(26) U.S.C.—United States Code.

[50 FR 16656, Apr. 26, 1985, as amended at 54 FR 9038, Mar. 3, 1989]

Subpart B—Agency Actions Requiring Environmental Consideration

§ 25.20 General procedures.

(a) These procedures apply to all FDA actions that are not covered by environmental documents prepared under FDA environmental regulations previously in effect.

(b) All agency actions are subject to environmental consideration. Actions are individually examined for potential environmental impact unless excluded as a class by categorical exclusion under § 25.24.

§ 25.21 Actions requiring preparation of an environmental impact statement.

(a) There are no categories of agency actions which routinely significantly affect the quality of the human environment and which therefore ordinarily require the preparation of an EIS.

(b) EIS's are prepared for agency actions when:

(1) Evaluation of data in an EA leads to a finding by the responsible agency official that a proposed action may significantly affect the quality of the human environment under the criteria in 40 CFR 1508.14 and 1508.27.

(2) Initial evaluation by the responsible agency official of any action, including any action for which an EA would otherwise be required, establishes that significant environmental effects may be associated with one or more of the probable courses of action being considered.

§ 25.22 Actions requiring preparation of an environmental assessment.

(a) Any proposed action of a type specified in this paragraph oridinarily requires the preparation of an EA, unless it qualifies for exclusion under §§ 25.23 and 25.24:

(1) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsiblity for the subject matter involved.

(2) Destruction or other disposition of articles condemned after seizure or whose distribution or use has been enjoined.

(3) Destruction or other disposition of articles following detention or recall at agency request.

(4) Disposition of FDA laboratory waste materials.

(5) Intramural and extramural research supported in whole or in part through contracts, other agreements, or grants.

(6) Establishment by regulation of labeling requirements, a standard, or a monograph.

(7) Amendments to, or an exemption or variance from, requirements of existing FDA regulations.

(8) Approval of supplements to existing approvals of FDA-approved articles.

(9) Withdrawal of existing approvals of FDA-approved articles.

(10) Approval of food additive petitions and color additive petitions and approval of requests for exemptions for investigational use of food additives.

(11) Establishment of a tolerance or an action level for unavoidable poisonous or deleterious substances in food or in packaging materials to be used for food.

(12) Affirmation of a food substance as generally recognized as safe (GRAS) for humans or animals, on FDA's initiative or in response to a petition, under Part 182, 184, 186, or 582.

(13) Promulgation and enforcement of FDA regulations relating to the control of communicable disease and to interstate conveyance sanitation.

(14) Approval of new drug applications (NDA's) and abbreviated new drug applications and actions on investigational new drug applications (IND's).

(15) Approval of antibiotic application.

(16) Approval and issuance of licenses for biological products.

(17) Approval of new animal drug applications (NADA's), supplements and amendments to NADA's, and notices of claimed investigational exemptions for new animal drugs (INAD's).

(18) Approval of premarket approval applications (PMA's) for medical devices, notices of completion of product development protocols (PDP's) for medical devices, authorizations to commence clinical investigation under an approved PDP, or applications for an investigational device exemption (IDE).

(19) Action other than one listed in this subsection, unless subject to exclusion under §§ 25.23 and 25.24, that may significantly affect the quality of the human environment.

(b) A person who submits an application or petition requesting action by the agency of a type specified in paragraph (a) of this section shall include an EA for the requested action in the applicable format in § 25.31, unless the action qualifies for exclusion under §§ 25.23 and 25.24. Failure to submit an adequate EA, if one is required, for such an action is sufficient grounds for FDA to refuse to file or approve the application or petition. An EA adequate for filing is one that addresses each of the items specified in the applicable format in § 25.31. An EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment.

(c) A manufacturer, distributor, or dealer who proposes to destroy or otherwise dispose of an FDA-regulated article that has been condemned, detained, or recalled, or whose distribution or use has been enjoined shall, if requested by the agency, submit an EA in the applicable format prescribed in § 25.31 analyzing the environmental impact of the proposed disposition of such article or shall provide information establishing that the action qualifies for exclusion under §§ 25.23 and 25.24.

(d) The responsible agency officials will evaluate the information contained in the EA to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS will be prepared. FDA is responsible for ensuring the accuracy of the EA, as required by 40 CFR 1506.5(b). If significant effects requiring the preparation of EIS are identified, FDA will publish in the FEDERAL REGISTER a Notice of Intent to prepare an EIS in accordance with § 25.33 of this part. If significant effects requiring the preparation of an EIS are not anticipated and the decision is made not to prepare an EIS, the responsible agency official will prepare a finding of no significant impact (FONSI) in accordance with § 25.32.

[50 FR 16656, Apr. 26, 1985, as amended at 54 FR 9038, Mar. 3, 1989]

§ 25.23 Actions that are excluded from the requirement to prepare an environmental assessment.

(a) Actions of a class that individually or cumulatively have been determined under § 25.24 not to significantly affect the quality of the human environment ordinarily are excluded from the preparation of an EA or an EIS.

(b) As required under 40 CFR 1508.4, FDA will require an EA for any specifc action that ordinarily is excluded if the agency has sufficient evidence to establish that the specific proposed action may significantly affect the quality of the human environment.

(c) A person submitting an application or petition of a type subject to categorical exclusion under § 25.24, or proposing to dispose of an article as provided in § 25.24 (a)(4) or (b)(9), is not required to submit an EA if the person specifies the provision of this part that excludes the action from the requirement for an EA and provides information, when appropriate, that establishes to the agency's satisfaction that the action requested is included within an excluded category and meets the criteria for the applicable exclusion.

(d) Failure to provide sufficient information, when appropriate, to establish that the requested action is subject to a categorical exclusion under § 25.24 may result in the agency's refusal to file or to approve the application or petition or to approve the proposed disposition of an article as provided in § 25.24 (a)(4) or (b)(9).

(Approved by the Office of Management and Budget under control number 0910-0190)

[50 FR 16656, Apr. 26, 1985, as amended at 50 FR 30267, July 25, 1985]

§ 25.24 Categorical exclusions.

Certain FDA actions listed in this section are subject to categorical exclusions and, therefore, ordinarily do not require the preparation of an EA because, as a class, these actions will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment. (These actions are listed in paragraphs (a) (1) through (3), (5), (7) through (9), (b) (1), (4) through (6), and 8(ii), (c) (3), (5), (8), (9), and (11), (d) (2), (3), and (5), (e) (1) through (3) and (5) of this section.) Additional exclusions for actions that will not result in the introduction of any substance into the environment are contained in Chapter 30-20-40 B.2. of the HHS General Administration Manual. Certain FDA actions listed in this section are subject to categorical exclusions and, therefore, ordinarily do not require the preparation of an EA because these actions meet specific criteria that are intended to ensure that they will not cause significant environmental effects. (These actions are listed in paragraphs (a) (4), (6), (10), and (11), (b) (2), (3), (7), (8)(i), and (9), (c) (1), (2), (4), (6), (7), and (10), (d) (1), (4), (6), and (7), (e) (4), (6), and (7) of this section.) Certain FDA actions listed in this section are subject to categorical exclusions and, therefore, ordinarily do not require the preparation of an EA because, as a class, these actions are routine maintenance or minor leasing or construction activities conducted or contracted for by FDA. (These actions are listed in paragraph (a)(12) of this section.) The classes of actions that are categorically excluded are as follows:

(a) *General.* (1) Routine administrative and management activities, including inspections, and issuance of field compliance programs, program circulars, or field investigative assignments.

(2) Recommendation for an enforcement action to be initiated in a Federal court.

(3) Agency requests for initiation of recalls.

(4) Destruction or disposition of any article condemned after seizure or the distribution or use of which has been enjoined or following detention or recall at agency request if the method of destruction or disposition of the article, including packaging material, will not result in the release of a toxic substance into the environment.

(5) Extramural contracts, other agreements, or grants for statistical and epidemiological studies, surveys and inventories, literature searches, and report and manual preparation, or any other studies that will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment.

(6) Extramural contracts, other agreements, and grants for research for such purposes as to develop analytical methods or other test methodologies if the waste from such research will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(7) Activities of voluntary Federal-State cooperative programs, including issuance of model regulations proposed for State adoption.

(8) Issuance, amendment, or revocation of procedural or administrative regulations and guidelines, including procedures for submission of applications for product development, testing and investigational use, and approval.

(9) Corrections and technical changes in regulations.

(10) Promulgation of current good manufacturing practice (CGMP) regulations, establishment standards, emergency permit control regulations, and good laboratory practice (GLP) regulations, and issuance or denial of permits, exemptions, variances, or stays under these regulations, if there is no increase in the quantities or toxicity of wastes entering the environment as a direct or indirect result of the action.

(11) Establishment or repeal by regulation of labeling requirements for marketing articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.

(12) Routine maintenance and minor construction activities, except for properties listed on or eligible for listing on the National Register of Historic Places:

(i) Repair to or replacement of equipment or structural components (doors, roof, window, etc.) of facilities controlled by FDA;

(ii) Lease extensions, renewals, or succeeding leases;

(iii) Construction or lease construction of 10,000 square feet or less of occupiable space;

(iv) Relocation of employees into existing owned or currently leased space;

(v) Acquisition of 20,000 square feet or less of occupiable space in a structure that was substantially completed before the issuance of solicitation for offers; and

(vi) Acquisition of between 20,000 square feet and 40,000 square feet of occupiable space if it constitutes less than 40 percent of the occupiable space in a structure that was substantially completed before the solicitation for offers.

(b) *Foods, food additives, and color additives.* (1) Promulgation, amendment, or repeal of a food standard.

(2) Action on a request for exemption for investigational use of a food additive if the food additive to be shipped under the request is intended to be used for clinical studies for research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(3) Approval of a color additive petition to change a provisionally listed color additive to permanent listing for use in food, drugs, devices, or cosmetics if data available to the agency do not establish that, at the expected

levels of exposure, it may be toxic to organisms in the environment.

(4) Testing and certification of batches of a color additive.

(5) Promulgation of an interim food additive regulation.

(6) Establishment of an action level under section 402(a) of the Federal Food, Drug, and Cosmetic Act for natural or unavoidable defects in food for humans or animals if these defects present no health hazard.

(7) Affirmation of a food substance as generally recognized as safe (GRAS) for humans or animals on FDA's initiative or in response to a petition, under Part 182, 184, 186, or 582, if the substance is already marketed for the use for which affirmation is sought and data available to the agency do not establish that, at the expected levels of exposure, the substance may be toxic to organisms in the environment.

(8) Promulgation and enforcement of regulations relating to the control of communicable diseases or to interstate conveyance sanitation under:

(i) Part 1240 if the method of control (including treatments, destruction, or disposition) of any animal or article, including packaging material, does not affect an endangered species or result in the release of a toxic substance into the environment; or

(ii) Part 1250 if the corrective measures do not result in the release of a toxic substance into the environment.

(9) Approval of a request for diversion of adulterated or misbranded food for humans or animals to use as animal feed if such disposition of the article, including packaging material, will not result in the release of a toxic substance into the environment.

(c) *Human drugs and biological products.* (1) Action on an ANDA if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected level of exposure, the substance may be toxic to organisms in the environment.

(2) Action on an amendment or supplement to an NDA of the following types if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected levels of exposure, the substance may be toxic to organisms in the environment.

(i) Changes specified in § 314.70 (c) or (d); or

(ii) Any other type of amendment or supplement to an NDA which meets the above criteria for exclusion.

(3) Withdrawal of approval of an NDA or ANDA when the drug is no longer being marketed or at the request of the application holder.

(4) Action on an Investigational New Drug Application (IND), if the drug shipped under such notice is intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(5) Testing and certification of batches of an antibiotic or insulin.

(6) Promulgation, revocation, or amendment of a monograph for a drug that is not a new drug, for an antibiotic drug, or for an over-the-counter (OTC) drug, if the drug is already marketed for the proposed use and data available to the agency do not establish that, at the expected levels of exposure, the drug may be toxic to organisms in the environment.

(7) Establishment of bioequivalence requirements for a marketed drug product if there is no change in the existing levels of use or intended uses of the product.

(8) Action on changes in a biological product license or an establishment license reported under § 601.12 of this chapter.

(9) Revocation of a license for a biological product when it is no longer being marketed, or revocation of a biological product or establishment license at the request of the license holder.

(10) Promulgation, amendment, or revocation of a standard for a licensed biological product or amendment of the license for a biological product if there is no change in the existing levels of use or intended uses of the product.

(11) Action on a license application for transfusable blood or blood products.

(d) *Animal drugs.* (1) Action on an NADA or supplemental NADA for a previously approved animal drug of the following types if the drug product will not be administered at higher dosage levels, for longer duration, or for different indications than were previously in effect and if data available to the agency do not establish that, at the expected level of exposure, the substance may be toxic to organisms in the environment:

(i) An animal drug to be marketed under the same conditions of approval as a previously approved animal drug;

(ii) A combination of previously approved animal drugs;

(iii) A new premix or other formulation of a previously approved animal drug;

(iv) Changes specified in § 514.8(a)(5), (6), or (d);

(v) A change of sponsor; or

(vi) A previously approved animal drug to be contained in medicated feed blocks under § 510.455 or as a liquid feed supplement under § 558.5.

(2) Approval of an animal feed bearing or containing a drug approved under § 514.2 or 514.9.

(3) Withdrawal of approval of an NADA when the drug is no longer being marketed or at the request of the application holder.

(4) Action on a notice of claimed investigational exemption for a new animal drug (INAD) if the drug to be shipped under such notices is intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(5) Testing and certification of batches of an antibiotic for animal use.

(6) Promulgation, revocation, or amendment of a monograph for an animal drug that is not a new animal drug, if the drug is already being marketed for the proposed use and data available to the agency do not establish that, at the expected levels of exposure, the drug may be toxic to organisms in the environment.

(7) Establishment of bioequivalence requirements for marketed animal drug products if there is no change in the existing levels of use or intended uses of the product.

(e) *Devices and electronic products.* (1) Action on a device premarket notification submission under Subpart E of Part 807.

(2) Classification or reclassification of a device under Part 860.

(3) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard.

(4) Approval of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device and data available to the agency do not establish that approval of the PMA, or the notice of completion of the PDP or amended or supplemental applications or notices, will result in release of substances that, at the expected levels of exposure, may be toxic to organisms in the environment.

(5) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(6) Promulgation of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(7) Action on an application for an Investigational Device Exemption (IDE) or an authorization to commence a clinical investigation under an approved Product Development Protocol (PDP), if the devices shipped under such notices are intended to be used for clinical studies or research in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be nontoxic.

(8) Promulgation of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

[50 FR 16656, Apr. 26, 1985, as amended at 54 FR 9038, Mar. 3, 1989]

§ 25.25 Retroactive environmental consideration.

(a) FDA may consider the need for preparing an EIS for an existing FDA regulation, approval, or other action, whether or not previously subject to environmental analysis, when there is new information before the agency that suggests that the action may significantly affect the quality of the human environment.

(b) If FDA notifies an applicant or petitioner who obtained an existing FDA approval that new information suggests that the approval may have signficant environmental effects and that an EA is therefore required, the applicant or petitioner shall submit an EA as described in § 25.31 for the approval. A notification under this paragraph will be in writing.

Subpart C—Preparation of Environmental Documents

§ 25.30 Content and format.

(a) Sections 25.31 through 25.34 describe the environmental documents that may be required in the course of the agency's consideration of the environmental aspects of an action. These sections delineate the relationships of these documents to each other and their purpose, contents, and format. Additional information concerning the nature and scope of information that an applicant or petitioner shall submit in an environmental document may be obtained on a case-by-case basis from the bureau, national center, or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA environmental assessment technical guides, which describe protocols for environmental studies and discuss the interpretation results.

(b) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360j(c) shall not be included in environmental documents prepared under this part. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner may submit such data and information separately as a confidential section of the application or petition, but shall summarize the confidential data and information in the environmental document to the extent possible.

§ 25.31 Environmental assessment formats.

(a) As defined by CEQ in 40 CFR 1508.9, the EA is the public document in which environmental and other pertinent information on a proposed action are presented, providing a basis for the agency's determination whether to prepare an EIS or a FONSI.

(b) An EA shall be prepared in the format presented in this section for each action not categorically excluded in § 25.24. The EA shall be a complete, objective, and well-balanced document that allows the public to understand the agency's decision.

(c) Consistent with 40 CFR 1500.4(j) and 1502.21, EA's may incorporate by reference information presented in other documents that are available to FDA and to the public.

§ 25.31a Environmental assessment for proposed approvals of FDA-regulated products—Format 1.

(a) For proposed actions to approve food or color additives, drugs, biological products, animal drugs, and class III medical devices, and to affirm food substances as generally recognized as safe (GRAS), the applicant or petitioner shall prepare an environmental assessment in the following format:

ENVIRONMENTAL ASSESSMENT

1. *Date*:

2. *Name of applicant/petitioner:*

3. *Address*:

4. *Description of the proposed action*: Briefly describe the requested approval; need for the action; the locations where the products will be produced; to the extent possible, the locations where the products will be used and disposed of; and the types of environments present at and adjacent to those locations.

5. *Identification of chemical substances that are the subject of the proposed action:* Provide complete nomenclature, CAS Reg. No. (if available), molecular weight, structural formulae, physical description, additives, and impurities. This information is required to be adequate to allow accurate location of data about chemicals in the scientific literature and to allow identification of closely related chemicals.

6. *Introduction of substances into the environment:* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval of the proposed action will have upon compliance with current emissions requirements at the production site(s). Through use of calculations and/or direct measures, estimate to the extent possible the quantities and concentrations of substances expected to enter the environment as a result of use and/or disposal of products affected by the action.

7. *Fate of emitted substances in the environment:* Predict environmental concentrations of and exposures to substances entering the environment as a consequence (direct or indirect) of the use and/or disposal of the products affected by the action for the following environmental compartments, including consideration of the major environmental transport and transformation processes involved:

(a) Air—taking into account, to the extent possible, factors such as volatilization, photochemical and chemical degradation, rainout, and dispersion;

(b) Freshwater, estuarine, and marine ecosystems—taking into account, to the extent possible, factors such as chemical and biological degradation, exchange between the water column and sediments via sorption/desorption and biological processes, accumulation in animals, plants, and other organisms, introductions due to rainfall and losses due to volatilization;

(c) Terrestrial ecosystems—taking into account, to the extent possible, factors such as chemical and biological degradation, sorption/desorption and leaching in soils, accumulation in animals and plants, introductions due to rainfall, losses due to volatilization, and entry into groundwater.

8. *Environmental effects of released substances:* Given the information developed on the introduction (item 6) and fate (item 7) of substances which would be released as a consequence of the use and/or disposal of the products affected by the action, use any relevant toxicological data or other appropriate measures to predict, to the extent applicable, effects on animals, plants, humans, other organisms, and effects at the ecosystem-level in each of the environmental compartments listed in item 7.

9. *Use of resources and energy:* Specify the natural resources, including land use, minerals, and energy, required to produce, transport, use, and/or dispose of a given amount of any product which is the subject of the action, including the resources and energy required to dispose of wastes generated from production, use, and/or disposal. Effects, if any, upon endangered or threatened species and upon property listed in or eligible for listing in the National Register of Historic Places must be discussed.

10. *Mitigation measures:* Describe measures taken to avoid or mitigate potential adverse environmental impacts associated with the proposed action.

11. *Alternatives to the proposed action:* If potential adverse environmental impacts have been identified for the proposed action, describe in detail the environmental impact of all reasonable alternatives to the proposed action (including no action, and including measures that FDA or another government agency could undertake as well as those the applicant/petitioner would undertake). Describe particularly those alternatives that will enhance the quality of the environment and avoid some or all of the adverse environmental impacts of the proposed action. Discuss the environmental benefits and risks of the proposed action. Discuss the environmental benefits and risks of each alternative.

12. *List of preparers:* Those persons preparing the assessment together with their qualifications (expertise, experience, professional disciplines) shall be listed. Persons and agencies consulted shall also be listed.

13. *Certification:* The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

(Date) ————————————

————————————————

(Signature of responsible official)

(Title) ————————————

14. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

15. *Appendices:* (a) Data summary charts (e.g., structural formula, vapor pressure, water solubility, *n*-octanol/water partition coefficient, biodegradation half-life, LC_{50} for each species tested, etc.).

(b) Test reports (for each experiment: research objective, experimental design and procedure, all data relevant to interpretation of the test result given in item 15(a), sample calculations and statistical analyses).

(b) FDA has determined that, for the following actions, certain requirements of the environmental assessment format in paragraph (a) of this section may be abbreviated as specified in this paragraph. All other format items in paragraph (a) of this section are required to be addressed in full. After FDA evaluates environmental information submitted in an EA in which one or more format items are abbreviated, FDA may require the submission of additional information on the subject in question.

(1) For actions to approve food additive petitions for food additives present in finished food-packaging material at not greater than 5-percent-by-weight, the following information is required for the format items specified:

(i) *Format item 6.* For the site(s) of production of the food additive, list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval will have upon compliance with current emissions requirements at the production site(s). For food additives that are present as functional components of finished food-packaging material, estimate the maximum yearly market volume of the additive for the proposed use and the percent of that amount that will be a component of the finished food-packaging material. This information may be used to determine whether the proposed additive has potential for significant environmental introductions at the sites of production and disposal of the food-packaging material. For food additives that are used in the production of and that become nonfunctional components of finished food-packaging material, estimate the maximum yearly market volume of the additive for the proposed use, the percent of that amount that will be a component of the finished food-packaging material, and the concentrations of the proposed food additive expected to enter the environment at the site of production of the food-packaging material. This information may be used to determine whether the proposed additive has potential for significant environmental introductions at the sites of production and disposal of the food-packaging material.

(ii) *Format item 7.* For food additives that become nonfunctional components of finished food-packaging material, report or incorporate by reference physical/chemical and other data relating to the environmental fate of the additive developed for other purposes in the petition and where pertinent data in the scientific literature are known. Examples of such physical/chemical parameters include water solubility, *n*-octanol/water partition coefficient, vapor pressure, etc. These data may be used to make a rough estimate of environmental concentration and mobility of the food additive at the site of production of the food-packaging material. Documentation of environmental fate is normally not required for food additives that are present as functional components of finished food-packaging material at not greater than 5-percent-by-weight.

(iii) *Format item 8.* For food additives that become nonfunctional components of food-packaging material, report or incorporate by reference existing data relating to the environmental effects of the proposed food additive. Toxicity of the proposed food additive to laboratory animals (submitted to satisfy human safety requirements) and information on the toxicity of the product to organisms that may be exposed in the environment, e.g., fish, invertebrates, plants, fungi, and bacteria, known from the scientific literature should be reported. The expected environmental concentrations of the proposed food additive should be compared with the concentrations that caused adverse toxicological effects. Documentation of environmental effects is normally not required for additives that are present as functional components of finished food-packaging material at not greater than 5-percent-by-weight.

(iv) *Format item 9.* Documentation for this item is ordinarily not required if the proposed food additive is intended for the same use as another additive already in use and will not materially change the potential uses of the packaging material to which it is added.

(v) *Format items 10 and 11.* For food additives that are present as functional components of finished food-packaging material at not greater than 5-percent-by-weight, documentation for these items is normally not required. For food additives that become nonfunctional components of finished food-packaging material at not greater than 5-percent-by-weight, these format items are addressed in full.

(2) For approval of food additives to be used as components of food-contact surfaces of permanent or semi-permanent equipment or of other food-contact articles intended for repeated use, the following information is required for the items specified:

(i) *Format item 6.* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval of the proposed food additive will have upon compliance with current emissions requirements at the production site(s). To determine whether approval of the proposed food additive will result in potentially significant introductions of substances into the environment due to the disposal of food-contact articles containing the proposed food additives, estimate the maximum yearly market volume of the proposed food additive.

(ii) *Format items 7 through 11 and 15.* Documentation for these items is ordinarily not required.

(3) For approval of NDA's for human drugs and approval of licenses for biological products, when the drugs or biological products are intended for the prevention, treatment, or diagnosis of a rare disease or for a similarly infrequent use; for ophthalmic or topical application; or for local or general anesthesia; the following information is required for the items specified:

(i) *Format item 6.* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval will have upon compliance with current emissions requirements at the production site(s). Estimate the maximum yearly market volume of the drug product to aid in determining whether approval of the application could result in potentially significant environmental introductions from use of the product.

(ii) *Format items 7 through 11 and 15.* Documentation for these items is ordinarily not required.

(4) For approval of NADA's and supplements and amendments to NADA's for animal drugs intended for use under prescription or veterinarian's order; for treatment of a disease occurring in minor species animals, as defined in § 514.1(d); for use in nonfood animals; for ophthalmic or topical application; or for local or general anesthesia; the following information is required for the format items specified:

(i) *Format item 6.* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; include a citation of, and statement of compliance with, applicable emissions requirements (including occupational) at the Federal, State, and local level; and discuss the effect the approval will have upon compliance with current emissions requirements at the production site(s). Estimate the maximum yearly market volume of the drug product to aid in determining whether approval of the application will result in potentially significant environmental introductions from use of the product.

(ii) *Format items 7 through 11 and 15.* Documentation for these items is ordinarily not required.

(5) When the agency approves or issues, for a substance that occurs naturally in the environment, a food or color additive petition, GRAS affirmation petition, NDA, supplemental NDA, biological product license, NADA, supplemental NADA, or class III medical device, the following information is required for the format items specified:

(i) *Format item 6.* For the site(s) of production: list the substances expected to be emitted; state the controls exercised; and include a citation of, and statement of compliance with, applicable emissions requirements at the Federal, State, and local level; and discuss the effect the approval will have upon compliance with current emissions requirements at the production site(s).

(ii) *Format item 7.* Discuss whether the use of the product can reasonably be expected on the basis of all available evidence to alter significantly the concentration and distribution of the product, its metabolites, degradation products, or its constituent parts in the environment.

(iii) *Format item 8.* Report existing data relating to the environmental effects of substances expected to be emitted into the environment as a consequence of use of the product. Report information obtained from the scientific literature on the toxicity of the product to laboratory animals, e.g., that information which is submitted to satisfy human safety requirements, and to organisms in the environment, e.g., fish, invertebrates, plants, fungi, and bacteria, that may be exposed to the product.

(6) For approval or issuance by the agency of a food or color additive petition, NDA, supplemental NDA, biological product license, NADA, or supplemental NADA for a product that has been approved by the Environmental Protection Agency (EPA) under section 4 or 5 of the Toxic Substances Control Act (TSCA) or under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the following information is required:

(i) *Format items 7 and 8.* To address these items, rely on environmental information in studies submitted to EPA, in the application/petition submitted for FDA approval, and in the scientific literature. Describe any potential adverse environmental impacts determined by EPA.

(ii) *Format item 15(b).* For studies submitted to EPA or for relevant studies submitted in the application/petition to meet the requirements of the Federal Food, Drug, and Cosmetic Act, test reports may include only a brief description and summary of results of each study in lieu of attaching complete test reports.

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[50 FR 16656, Apr. 26, 1985, as amended at 50 FR 30267, July 25, 1985]

§ 25.31b Environmental assessment for withdrawals of approval and other restrictions—Format 2.

For proposed actions to withdraw approval or otherwise restrict or reduce the use of food or color additives, drugs, biological products, animal drugs, and class III medical devices, any environmental assessment prepared by the agency will be in the following format:

ENVIRONMENTAL ASSESSMENT

1. *Description of the proposed action:* Describe the proposed action, the regulatory authority for the proposed action, the underlying purpose of and need for the proposed action, and how the proposed action addresses the underlying purpose and need for action.

2. *Environmental consequences of the proposed action:* Describe the uses and the magnitude (production volume and/or sales) of such uses for the product(s) for which approval would be withdrawn or otherwise restricted or reduced and for the available substitute products. Determine those uses of the restricted product(s) for which no substitute products are available and the magnitude and essentiality of such uses. Discuss the environmental impacts of (1) reducing or eliminating environmental exposures to the restricted product; (2) natural resources and energy used in producing, distributing, using, and disposing of the restricted product compared with those required for the available substitute products; (3) any expected increased production and use of substitute products; and (4) essential uses of the restricted product for which there would be no substitutes.

3. *Mitigation measures:* Describe measures which would be taken to avoid or mitigate potential adverse environmental effects associated with the proposed action.

4. *Description of regulatory alternatives to the proposed action and the expected environmental consequences:* Describe in detail the environmental impact of reasonable alternatives to the proposed action (including no action), particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action.

5. *Comparative analysis of proposed action and alternatives:* Provide a comparative analysis of the environmental benefits and risks of the proposed action and alter-

natives. Identify the preferred action based on environmental factors.

6. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall be listed.

7. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

8. *Appendices:* Append detailed physical, chemical, biological, and environmental data on products that are the subject of the proposed action.

§ 25.31c Environmental assessment format for extramural contracts, grants, or other research agreements—Format 3.

For extramural contracts, grants, or other research agreements subject to environmental assessment, the contractor or applicant shall use the following format:

ENVIRONMENTAL ASSESSMENT

1. *Date:*

2. *Name of prospective contractor/ applicant:*

3. *Address:*

4. *Description of the proposed research activities:* Briefly describe the purpose of the proposed research, the locations where the research activities would occur, and the types of environments present at those locations.

5. *Information on the chemical substances and infectious agents to be used:* Provide the information listed in Table 1 on each of the chemical substances and infectious agents to be used in the research activity, to the extent that they can be identified, either specifically or generically, and including such items as organic solvents as well as the chemicals of major research interest.

TABLE 1.—CHEMICAL SUBSTANCES/INFECTIOUS AGENTS TO BE USED IN THE PROPOSED RESEARCH ACTIVITIES

Chemical infectious agent name (complete scientific nomenclature	Approximate amounts to be used [a]	Hazard code [b]	Emissions controls: (environmental and occupational) [c]
1.			
2.			
3.			

[a] Specify in metric units of mass or volume.

[b] I—infectious, C—carcinogenic, M—mutagenic, T—teratogenic, A—acutely toxic or poison, COR—corrosive, E—explosive or flammable, R-radioactive, O-other hazard, please specify, NH-nonhazardous.

[c] Examples include use of fume hoods, use of protective clothing/gear by laboratory personnel, chemical inactivation of wastes, separation of hazardous from nonhazardous wastes, and subsequent disposal by a firm licensed for this purpose.

6. *Compliance with Federal, State, and local environmental and occupational requirements.* Cite and include a statement of compliance with applicable emissions requirements (including occupational) at the Federal, State, and local level. Discuss the effect that the proposed research will have upon compliance with these requirements.

7. *List of preparers:* Those persons preparing the assessment together with their qualifications (expertise, experience, professional disciplines) shall be listed. Persons and agencies consulted shall also be listed.

8. *Certification:* The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the prospective contractor or applicant submitting the environmental assessment.

(Date) ——————————————

——————————————

(Signature of responsible official)

(Title) ——————————————

(Approved by the Office of Management and Budget under control number 0910-0190)

[50 FR 16656, Apr. 26, 1985, as amended at 50 FR 30267, July 25, 1985]

§ 25.31d Environmental assessment for establishment of tolerances or action levels—Format 4.

For proposed actions to establish tolerances or action levels for unavoidable poisonous or deleterious substances in food for human or animal consumption or in packaging materials intended for use with human food and animal feed, the agency will prepare an environmental assessment in the following format:

ENVIRONMENTAL ASSESSMENT

1. *Description of the proposed action:* Describe the proposed action, the regulatory authority for the proposed action, the underlying purpose of and need for the proposed action, and how the proposed action addresses the underlying purpose and need for action.

2. *Environmental consequences of the proposed action:* Describe the potential environmental impacts of the proposed action including effects on natural resources and energy, effects on food production, effects on land use, and impacts resulting from increased use and changes in use patterns for chemical substances.

3. *Mitigation measures:* Describe measures which would be taken to avoid or mitigate

potential adverse environmental effects associated with the proposed action.

4. *Description of regulatory alternatives to the proposed action and the expected environmental consequences:* Describe in detail the environmental impact of reasonable alternatives to the proposed action (including no action), particularly those that will enhance the quality of the environment and avoid some or all of the adverse environmental effects of the proposed action.

5. *Comparative analysis of proposed action and alternatives:* Provide a comparative analysis of the environmental benefits and risks of the proposed action and alternatives. Identify the preferred action based on environmental factors.

6. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

7. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

§ 25.31e Environmental assessment for destruction of condemned, enjoined, detained, or recalled articles—Format 5.

For actions to destroy or dispose of articles condemned after seizure, detention, or FDA-initiated recall, or after distribution or use of the article has been enjoined, the person proposing the action shall, at the request of the agency, prepare an environmental assessment in the following format when the method of destruction or disposition results in release of toxic substances:

ENVIRONMENTAL ASSESSMENT

1. *Purpose of and need for action:* Briefly describe the underlying purpose and need for the article to be destroyed, the proposed method of destruction or disposal, the locations where the proposed destruction or other disposal will occur, and the types of environments present at and adjacent to those locations.

2. *Description of potentially toxic substances present in the article:* Provide complete nomenclature, CAS Registry numbers (if available), molecular weight, structural formulae, physical description, and concentration of the potentially toxic substances in the article.

3. *Introduction of potentially toxic substances into the environment:* For transport of the article to the site(s) of disposition, cite and certify compliance with any applicable Federal, State, and local emissions requirements. List to the extent possible the potentially toxic substances expected to enter the environment at the site(s) of destruction and/or disposal of the article. Describe the approximate concentrations of emissions; state the controls exercised; and include a citation of, and statement of compliance with, applicable requirements at the Federal, State, and local level.

4. *Fate of potentially toxic emitted substances in the environment:* Report physical/chemical and other data in the scientific literature relating to the fate of potentially toxic substances expected to be emitted into the environment as a result of destruction or other disposal of the article. Such physical/chemical parameters include water solubility, solubility in organic solvents, *n*-octanol/water partition coefficient, dissociation constants, vapor pressure, ultraviolet-visible absorption spectrum, ability to form chemical complexes, storage stability, etc.

5. *Environmental effects of potentially toxic substances expected to be emitted into the environment.* Report information on the effects of the emitted substances on animals, plants, humans, other organisms, and effects at the ecosystem level. Compare the expected environmental concentrations of the substances with the concentrations that cause adverse effects.

6. *Description of alternative methods of destruction and/or disposal and the expected environmental consequences:* Describe the environmental impact of reasonable alternatives (including no action) particularly those that will enhance the quality of the environment and that will avoid some or all of the adverse environmental effects of the proposed method of destruction or other disposition.

7. *Comparative analysis of proposed methods of destruction or other disposition and alternative methods:* Provide a comparative analysis of the environmental benefits and risks of the proposed and alternative methods. Identify the preferred action based on environmental factors.

8. *List of preparers:* Those persons preparing the assessment and their areas of expertise shall be presented. Persons and agencies consulted shall also be listed.

9. *References:* List complete citations for all referenced material. Copies of referenced articles not generally available should be attached.

(Approved by the Office of Management and Budget under control number 0910-0190)

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§ 25.32 Finding of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a finding of no significant impact (FONSI) is a document prepared by a Federal agency and stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) If the EA has been prepared by an applicant or petitioner, the agency may choose to include additional evidence in the FONSI. Any remaining unknowns or uncertainties will be identified.

(c) The agency official(s) responsible for the preparation and approval of the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusions not to prepare an EIS for the action under consideration.

§ 25.33 Notice of intent.

(a) As defined by CEQ regulations (40 CFR 1508.22), the Notice of Intent notifies the public that the agency has determined that an EIS will be prepared. This determination may be based on information contained in an EA or on other information available to the agency which indicates that potentially significant effects may be associated with a proposed action.

(b) As required by 40 CFR 1508.22, the Notice of Intent will describe the proposed action, possible alternatives, the agency's proposed scoping process, which may include a request for information or suggestions regarding the scope of the EIS and notice of public meetings, and the identification of persons within the agency to contact for further information.

§ 25.34 Draft, final, and supplemental environmental impact statements.

(a) The CEQ regulations (40 CFR Part 1502) provide detailed requirements for the preparation of an EIS. CEQ's format for EIS's (40 CFR 1502.10) will be followed unless the agency determines that there is a compelling reason to do otherwise.

(b) When chemical substances enter the environment as a result of a proposed action or other regulatory alternatives, the portion of the EIS format on "environmental consequences" (40 CFR 1502.10(g)) will include discussion of the environmental fates and effects of those substances similar to that described in § 25.31a.

(c) Any final EIS will contain any additional information gathered by the agency after the publication of the draft EIS, a copy of or a summary of the comments received on the draft EIS, and the agency's responses to the comments as required in 40 CFR 1503, including any revisions resulting from comments or other information.

(d) Draft and final supplemental EIS's will conform to the EIS format (40 CFR 1502.10) unless there is a compelling reason to do otherwise.

Subpart D—Agency Decisionmaking

§ 25.40 Procedures for incorporating environmental considerations into agency decisionmaking.

(a) These procedures are to ensure that environmental information is provided to decisionmakers in a timely manner. The NEPA process is an integral part of FDA's decisionmaking. Agency decisionmakers ensure that the policies and purpose of NEPA and CEQ regulations are complied with by:

(1) Completing or assuring the completion of an EA, determining whether an EIS is required and, ordinarily, completing a draft EIS (if one is required) prior to or at the time of proposing an action subject to §§ 25.21 and 25.22.

(2) Including in decision documents and supporting environmental documents a discussion of all alternatives considered in the decision as required by 40 CFR 1502.14. Every action memorandum proposing an agency action included under § 25.21 or § 25.22 will contain an evaluation of the environmental impact of the proposed action and will be accompanied by a draft or final EIS if one is required.

(3) Submitting relevant environmental documents, comments, and responses with other decision documents through the review process.

(4) Including in the records of proceedings any appropriate environmental documents, comments, and responses.

(5) Completing and circulating a final EIS before the decision to imple-

ment an action that significantly affects the quality of the human environment.

(b) There are certain regulatory actions which, because of their immediate importance to the public health, make adherence to the requirements of the CEQ regulations and these regulations concerning minimum periods of public review impractical. Compliance with the requirements for environmental analysis under NEPA is impossible where emergency circumstances require immediate regulatory action to safeguard the public health. For such actions, the responsible agency official shall consult with the CEQ about alternative arrangements before the action is taken, or after the action is taken, if time does not permit prior consultation with CEQ.

(c) Certain FDA actions are subject to statutory time limits that sometimes do not provide sufficient time to complete the required environmental document. Should the responsible agency official be unable to complete environmental consideration of the proposed action before a notice of filing of a food or color additive petition is required to be published, and if the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the FEDERAL REGISTER document publishing the final regulation rather than the notice of filing shall state that no EIS is necessary and that the FONSI and the EA are available upon request and filed in the FDA Dockets Management Branch. If it is concluded that an EIS is necessary, the final regulation, final EIS, and record of decision shall be made available as prescribed in 40 CFR 1506.10.

§ 25.41 Actions for which a finding of no significant impact and an environmental assessment are prepared.

(a) As required by 40 CFR 1501.4(e), a FONSI is prepared for an individual action or groups of related actions that will not significantly affect the quality of the human environment. If potentially adverse environmental impacts are identified for an action or group of related actions, the EA supporting the FONSI will, as required by 40 CFR 1508.9, include a consideration of any reasonable alternative courses of action that offer less environmental risk or that are environmentally preferable to the proposed action.

(b) FONSI's and EA's will be available to the public in accordance with 40 CFR 1506.6 as follows:

(1) When the proposed action is the subject of a notice of proposed rulemaking or a notice of filing published in the FEDERAL REGISTER, the notice shall state that no EIS is necessary and that the FONSI and the EA are available for public inspection at the FDA Dockets Management Branch.

(2) For actions for which notice is not published in the FEDERAL REGISTER, the FONSI and the EA shall be made available to the public upon request according to the procedures in 40 CFR 1506.6.

(3) For a limited number of actions, the agency may make the FONSI and EA available for public review (including review by State and areawide information clearinghouses) for 30 days before the agency makes its final determination whether to prepare an EIS and before the action may begin, as described in 40 CFR 1501.4(e). This procedure will be followed when the proposed action is, or is closely similar to, one that normally requires an EIS or when the proposed action is one without precedent.

(c) Program area officials and environmental staff prepare or ensure that the information contained in an EA is complete and accurate, and they prepare the FONSI. The responsible agency official designated in Part 5 examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action.

§ 25.42 Actions for which an environmental impact statement is prepared.

(a) An individual action or group of related actions requires the preparation of an EIS when significant environmental impacts may be associated with one or more of the probable courses of action. The responsible agency official weighs any environmental impacts of each alternative course of action, including possible mitigation measures, and selects the course of action that is consistent with the applicable law and the agency's environmental analysis of the action.

(b) For actions for which an EIS is prepared, the public has the opportunity to offer comments and otherwise participate in the NEPA process as set forth in 40 CFR 1506.6 from the time the decision is made to prepare the document as described in this paragraph:

(1) A Notice of Intent to prepare an EIS is prepared for publication in the FEDERAL REGISTER and serves as the first public notification that an EIS will be prepared.

(2) The scoping process, as announced in the Notice of Intent, allows the public and Federal, State, and local government agencies to participate in determining the issues to be considered in the EIS.

(3)(i) Draft EIS's are filed with the EPA, sent to parties having an interest in the document, and are available to the public upon request for the purpose of receiving substantive comment, corrections, and additional information on the issues covered.

(ii) If the subject of a draft EIS is also the subject of a notice of proposed rulemaking, the FEDERAL REGISTER notice of proposed rulemaking will state that the draft EIS is available upon request, and will solicit comments from all interested persons.

(iii) If the subject of a draft EIS is not also the subject of a notice of proposed rulemaking published in the FEDERAL REGISTER, FDA will publish a notice in the FEDERAL REGISTER describing the proposed action and possible alternatives, stating that the draft EIS is available upon request, and soliciting comments from all interested persons.

(iv) FDA will solicit comments from any Federal agency having jurisdiction by law or having expertise on the environmental impact of a proposed action by sending it a copy of a draft EIS.

(v) Two copies of all comments on draft EIS's shall be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857 (except individuals may submit one copy) where they will be available for public inspection from 9 a.m. to 4 p.m., Monday through Friday.

(vi) Draft EIS's will be prepared, forwarded to EPA for filing, and made available to the public early enough in the consideration of the proposed action to permit meaningful review of the environmental issues involved. Except in emergencies, no final action will be taken on the proposal earlier than 90 days after a draft EIS has been prepared, forwarded to the EPA, and made available to the public.

(4) The final text of an EIS will be prepared by the responsible agency official after comments on the draft statement have been reviewed and will receive full consideration in the agency's decisionmaking process. The responsible agency official will forward 10 copies of the final statement to the Office of the Secretary of the Department of Health and Human Services and 10 copies to the EPA, and FDA will make copies of the final statement available for public inspection in the Dockets Management Branch. Copies of each final EIS will be available upon request and will be forwarded to those persons who submitted comments on the pertinent draft statements.

(5)(i) The weighing of any environmental impacts of alternatives in selecting a final course of action, as described in paragraph (a) of this section, will be reflected in the agency record of formal decisionmaking as required by 40 CFR 1505.2.

(ii) Except in emergencies, no agency action will be effective earlier than 30 days after the final statement has been filed for public inspection by EPA. If the subject of a final statement is also the subject of a regulation published in the FEDERAL REGISTER, this requirement may be met by simultaneous publication of the regulation and of a notice of availability of the final statement and the record of decision, provided that the regulation becomes effective no sooner than 30 days after the date of publication.

(iii) If the subject of an EIS is an FDA action governed by specific time requirements under statute or regulations, those time requirements will be extended, if at all, only as long as necessary to permit the agency to consider or issue an EIS for the action.

(c) As described in 40 CFR 1505.3, the agency may provide for monitoring to ensure that its decisions, any mitigating measures, and other conditions are carried out.

(d) Under the conditions prescribed in 40 CFR 1502.9(c), the agency will prepare a supplement for a draft or final EIS and introduce the supplement into its administrative record.

(e)(1) The agency official to whom authority for the action is delegated in Part 5 will ensure both that there is balancing of environmental impacts with the agency's objective in choosing an appropriate course of action and that the public is involved and notified of the decision, as described in paragraphs (a) through (d) of this section.

(2)(i) The director of each FDA center is responsible for preparing a draft or final EIS on actions delegated to that center by the Commissioner under Subpart B of Part 5 of this chapter or in which the center is a party in an administrative proceeding under Part 12, 13, 14, 15, or 16 of this chapter in which a draft or final EIS is required.

(ii) The Director, Office of Regional Operations, FDA, is responsible for preparing a draft or final EIS on the destruction of articles condemned after seizure, subject to an injunction, under import detention, or under detention or recalled at agency request.

(iii) The Office of the Commissioner of Food and Drugs is responsible for preparing or assigning the task of preparing a draft or final EIS on actions not otherwise assigned in this section.

Subpart E—Other Requirements

§ 25.50 Environmental effects abroad of major agency actions.

(a) In accordance with E.O. 12114, "Environmental Effects Abroad of Major Federal Actions" of January 4, 1979 (44 FR 1957, Jan. 9, 1977), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

(1) Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere.

(2) Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine in accordance with section 2-3 of the Executive Order whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine in accordance with section 2-4(a) and (b) of the Executive Order, whether the subject action calls for:

(1) An EIS;

(2) A bilateral or multilateral environmental study; or

(3) A concise environmental review.

(d) In preparing environmental documents under this subpart, the responsible official shall:

(1) Determine, as provided in section 2-5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and modification in contents, timing, and availability of documents.

(2) Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.

PART 50—PROTECTION OF HUMAN SUBJECTS

Subpart A—General Provisions

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Subpart B—Informed Consent of Human Subjects

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Subpart C—Protections Pertaining to Clinical Investigations Involving Prisoners as Subjects

50.40 Applicability.
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50.44 Restrictions on clinical investigations involving prisoners.
50.46 Composition of institutional review boards where prisoners are involved.
50.48 Additional duties of the institutional review boards where prisoners are involved.

AUTHORITY: Secs. 201, 406, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 701(a), 706, and 801, Pub. L. 717, 52 Stat. 1040-1042 as amended, 1049-1054 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 76 Stat. 974-795 as amended, 90 Stat. 540-560, 562-574 (21 U.S.C. 321, 346, 348, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371(a), 376, and 381); secs. 215, 351, 354-360F, Pub. L. 410, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n); 21 CFR 5.10.

SOURCE: 45 FR 36390, May 30, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 50.1 Scope.

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., Parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 406, 409, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 706, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

[45 FR 36390, May 30, 1980; 46 FR 8979, Jan. 27, 1981]

§ 50.3 Definitions.

As used in this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201—902, 52 Stat. 1040 et seq. as amended (21 U.S.C. 321—392)).

(b) "Application for research or marketing permit" includes:

(1) A color additive petition, described in Part 71.

(2) A food additive petition, described in Parts 171 and 571.

(3) Data and information about a substance submitted as part of the procedures for establishing that the substance is generally recognized as safe for use that results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.30 and 570.30.

(4) Data and information about a food additive submitted as part of the procedures for food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) Data and information about a substance submitted as part of the procedures for establishing a tolerance

for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in Part 312 of this chapter.

(7) A new drug application, described in Part 314.

(8) Data and information about the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in Part 320.

(9) Data and information about an over-the-counter drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in Part 330.

(10) Data and information about a prescription drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in this chapter.

(11) Data and information about an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for these drugs, described in § 314.300 of this chapter.

(12) An application for a biological product license, described in Part 601.

(13) Data and information about a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, described in Part 601.

(14) Data and information about an in vitro diagnostic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in Part 809.

(15) An "Application for an Investigational Device Exemption," described in Part 812.

(16) Data and information about a medical device submitted as part of the procedures for classifying these devices, described in section 513.

(17) Data and information about a medical device submitted as part of the procedures for establishing, amending, or repealing a standard for these devices, described in section 514.

(18) An application for premarket approval of a medical device, described in section 515.

(19) A product development protocol for a medical device, described in section 515.

(20) Data and information about an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in section 358 of the Public Health Service Act.

(21) Data and information about an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in § 1010.4.

(22) Data and information about an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in § 1010.5.

(c) "Clinical investigation" means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of Part 58 of this chapter, regarding nonclinical laboratory studies.

(d) "Investigator" means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(e) "Sponsor" means a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(f) "Sponsor-investigator" means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency.

(g) "Human subject" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

(h) "Institution" means any public or private entity or agency (including Federal, State, and other agencies). The word "facility" as used in section 520(g) of the act is deemed to be synonymous with the term "institution" for purposes of this part.

(i) "Institutional review board" (IRB) means any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. The term has the same meaning as the phrase "institutional review committee" as used in section 520(g) of the act.

(j) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(k) "Test article" means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

(l) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(m) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 513—516, 518—520, 701(a), 706, and 801, 52 Stat. 1049—1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511—517 as amended, 72 Stat. 1785—1788 as amended, 74 Stat. 399—407 as amended, 76 Stat. 794—795 as amended, 90 Stat. 540—560, 562—574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c—360f, 360h—360j, 371(a), 376, and 381); secs. 215, 301, 351, 354—360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173—1186 as amended (42 U.S.C. 216, 241, 262, 263b—263n))

[45 FR 36390, May 30, 1980, as amended at 46 FR 8950, Jan. 27, 1981; 54 FR 9038, Mar. 3, 1989]

Subpart B—Informed Consent of Human Subjects

AUTHORITY: Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 513—516, 518—520, 701(a), 706, and 801, 52 Stat. 1049—1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511—517 as amended, 72 Stat. 1785—1788 as amended, 74 Stat. 399—407 as amended, 76 Stat. 794—795 as amended, 90 Stat. 540—560, 562—574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360c—360f, 360h—360j, 371(a), 376, and 381); secs. 215, 301, 351, 354—360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173—1186 as amended (42 U.S.C. 216, 241, 262, 263b—263n)).

SOURCE: 46 FR 8951, Jan. 27, 1981, unless otherwise noted.

§ 50.20 General requirements for informed consent.

Except as provided in § 50.23, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

§ 50.21 Effective date.

The requirements for informed consent set out in this part apply to all human subjects entering a clinical investigation that commences on or after July 27, 1981.

§ 50.23 Exception from general requirements.

(a) The obtaining of informed consent shall be deemed feasible unless, before use of the test article (except as provided in paragraph (b) of this section), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

(1) The human subject is confronted by a life-threatening situation necessitating the use of the test article.

(2) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.

(3) Time is not sufficient to obtain consent from the subject's legal representative.

(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

(b) If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph (a) of this section in advance of using the test article, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

(c) The documentation required in paragraph (a) or (b) of this section shall be submitted to the IRB within 5 working days after the use of the test article.

§ 50.25 Elements of informed consent.

(a) *Basic elements of informed consent.* In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) *Additional elements of informed consent.* When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

(d) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

§ 50.27 Documentation of informed consent.

(a) Except as provided in § 56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in § 56.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

(2) A "short form" written consent document stating that the elements of informed consent required by § 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

Subpart C—Protections Pertaining to Clinical Investigations Involving Prisoners as Subjects

EFFECTIVE DATE NOTE: At 46 FR 35085, July 7, 1981, the effective date of Subpart C was stayed until further notice.

§ 50.40 Applicability.

(a) The regulations in this subpart apply to all clinical investigations involving prisoners as subjects that are regulated by the Food and Drug Administration under sections 505(i), 507(d), or 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations involving prisoners that support applications for research or marketing permits for products regulated by the Food and Drug Administration.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects to the extent such research is limited or barred by applicable State or local law.

§ 50.42 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 50.44 Restrictions on clinical investigations involving prisoners.

(a) Except as provided in § 50.44(b), clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 505(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration may not involve prisoners as subjects.

(b) Clinical investigations that are regulated by the Food and Drug Administration under sections 505(i), 507(d), or 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, may involve prisoners as subjects only if the institution responsible for the conduct of the clinical investigation has certified to the Food and Drug Administration that the institutional review board has approved the clinical investigation under § 50.48; and

(1)(i) In the judgment of the Food and Drug Administration, the proposed clinical investigation involves solely research on practices both innovative and accepted, which have the intent and reasonable probability of improving, the health and well-being of the subjects;

(ii) In cases in which these studies require the assignment of prisoners in a manner consistent with protocols approved by the institutional review board to control groups that may not benefit from the research, the study may proceed only after the Food and Drug Administration has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the FEDERAL REGISTER of its intent to approve such research; or

(2) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis, which is much more prevalent in prisons than elsewhere) provided that the Food and Drug Administration has consulted with appropriate experts, including experts in penology, medicine, and ethics, and has published notice in the FEDERAL REGISTER of its intent to approve such research; subject to the approval of the Food and Drug Administration, prisoners may participate in the research even though they are assigned, in a manner consistent with protocols approved by the institutional review board, to control groups that may not benefit from the research.

§ 50.46 Composition of institutional review boards where prisoners are involved.

In addition to satisfying any other requirements governing institutional review boards set forth in this chapter, an institutional review board, in carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the institutional review board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the institutional review board.

(b) At least one member of the institutional review board shall be a prisoner, or a prisoner advocate with appropriate background and experience to serve in that capacity, except that if a particular research project is reviewed by more than one institutional review board, only one institutional review board need satisfy this requirement.

§ 50.48 Additional duties of the institutional review boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for institutional review boards under this chapter, the institutional review board shall review clinical investigations covered by this subpart and approve such clinical investigations only if it finds that:

(1) The research under review represents one of the categories of research permitted under § 50.44(b) (1) and (2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the clinical investigation, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison, are not of such a magnitude that his or her ability to weigh the risks of the clinical investigation against the value of such advantages in the limited-choice environment of the prison is impaired;

(3) The risks involved in the clinical investigation are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners; unless the principal investigator provides to the institutional review board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that research project;

(5) Any information given to subjects is presented in language which is appropriate for the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the clinical investigation in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the clinical investigation will have no effect on his or her parole; and

(7) Where the institutional review board finds there may be need for followup examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The institutional review board shall carry out such other duties as may be assigned by the Food and Drug Administration.

(c) The institution shall certify to the Food and Drug Administration, in such form and manner as the Food and Drug Administration may require, that the duties of the institutional review board under this section have been fulfilled.

PART 56—INSTITUTIONAL REVIEW BOARDS

Subpart A—General Provisions

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AUTHORITY: Secs. 201, 406, 408, 409, 501, 502, 503, 505, 506, 507, 510, 513-516, 518-520, 701(a), 706, and 801, Pub. L. 717, 52 Stat. 1040-1042 as amended, 1049-1054 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-518 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 76 Stat. 794-795 as amended, 90 Stat. 540-546, 560, 562-574 (21 U.S.C. 321, 346, 346a, 348, 351, 352, 353, 355, 356, 357, 360, 360c-360f, 360h-360j, 371(a), 376, and 381); secs. 215, 301, 351, 354-360F, Pub. L. 410, 58 Stat. 690, 702 as amended 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 241, 262, 263b-263n); 21 CFR 5.10.

SOURCE: 46 FR 8975, Jan. 27, 1981, unless otherwise noted.

Subpart A—General Provisions

§ 56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i), 507(d), and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 56.102 Definitions.

As used in this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-392)).

(b) "Application for research or marketing permit" includes:

(1) A color additive petition, described in Part 71.

(2) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for a use which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in § 170.35.

(3) A food additive petition, described in Part 171.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) Data and information regarding a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in Part 312 of this chapter.

(7) A new drug application, described in Part 314.

(8) Data and information regarding the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in Part 320.

(9) Data and information regarding an over-the-counter drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in Part 330.

(10) Data and information regarding an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for such drugs, described in § 314.300 of this chapter.

(11) An application for a biological product license, described in Part 601.

(12) Data and information regarding a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, as described in Part 601.

(13) An "Application for an Investigational Device Exemption," described in Parts 812 and 813.

(14) Data and information regarding a medical device for human use submitted as part of the procedures for classifying such devices, described in Part 860.

(15) Data and information regarding a medical device for human use submitted as part of the procedures for establishing, amending, or repealing a standard for such device, described in Part 861.

(16) An application for premarket approval of a medical device for human use, described in section 515 of the act.

(17) A product development protocol for a medical device for human use, described in section 515 of the act.

(18) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such products, described in section 358 of the Public Health Service Act.

(19) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in § 1010.4.

(20) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in § 1010.5.

(21) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in Subpart D of Part 1003.

(c) "Clinical investigation" means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of Part 58, regarding nonclinical laboratory studies. The terms "research," "clinical research," "clinical study," "study," and "clinical investigation" are deemed to be synonymous for purposes of this part.

(d) "Emergency use" means the use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

(e) "Human subject" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

(f) "Institution" means any public or private entity or agency (including Federal, State, and other agencies). The term "facility" as used in section 520(g) of the act is deemed to be synonymous with the term "institution" for purposes of this part.

(g) "Institutional Review Board (IRB)" means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase "institutional review committee" as used in section 520(g) of the act.

(h) "Investigator" means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(i) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) "Sponsor" means a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(k) "Sponsor-investigator" means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., it does not include a corporation or agency. The obligations of a sponsor-investigator under this part include both those of a sponsor and those of an investigator.

(l) "Test article" means any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act.

[46 FR 8975, Jan. 27, 1981, as amended at 54 FR 9038, Mar. 3, 1989]

§ 56.103 Circumstances in which IRB review is required.

(a) Except as provided in §§ 56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in Parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

(b) Except as provided in §§ 56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

[46 FR 8975, Jan. 27, 1981; 46 FR 14340, Feb. 27, 1981]

§ 56.104 Exemptions from IRB requirement.

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

§ 56.105 Waiver of IRB requirement.

On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities or for classes of research activities, otherwise covered by these regulations.

Subpart B—Organization and Personnel

§ 56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other parts of this chapter, the IRB should include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely of men, or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Subpart C—IRB Functions and Operations

§ 56.108 IRB functions and operations.

In order to fulfill the requirements of these regulations, each IRB shall:

(a) Follow written procedures (1) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution, (2) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review, (3) for insuring prompt reporting to the IRB of changes in a research activity, (4) for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects; and (5) for insuring prompt reporting to the IRB of unanticipated problems involving risks to subjects or others.

(b) Except when an expedited review procedure is used (see § 56.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Food and Drug Administration any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

§ 56.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 50.25. The IRB may require that information, in addition to that specifically mentioned in § 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent in accordance with § 50.27, except that the IRB may, for some or all subjects, waive the requirement that the subject or the subject's legally authorized representative sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§ 56.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Food and Drug Administration has established, and published in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the FEDERAL REGISTER.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 56.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Food and Drug Administration may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§ 56.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are con-

sistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by Part 50.

(5) Informed consent will be appropriately documented, in accordance with and to the extent required by § 50.27.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 56.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 56.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.

§ 56.114 Cooperative research.

In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

Subpart D—Records and Reports

§ 56.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a writ-

ten summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.

(6) Written procedures for the IRB as required by § 56.108(a).

(7) Statements of significant new findings provided to subjects, as required by § 50.25.

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

(c) The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

Subpart E—Administrative Actions for Noncompliance

§ 56.120 Lesser administrative actions.

(a) If apparent noncompliance with these regulations in the operation of an IRB is observed by an FDA investigator during an inspection, the inspector will present an oral or written summary of observations to an appropriate representative of the IRB. The Food and Drug Administration may subsequently send a letter describing the noncompliance to the IRB and to the parent institution. The agency will require that the IRB or the parent institution respond to this letter within a time period specified by FDA and describe the corrective actions that will be taken by the IRB, the institution, or both to achieve compliance with these regulations.

(b) On the basis of the IRB's or the institution's response, FDA may schedule a reinspection to confirm the adequacy of corrective actions. In addition, until the IRB or the parent institution takes appropriate corrective action, the agency may:

(1) Withhold approval of new studies subject to the requirements of this part that are conducted at the institution or reviewed by the IRB;

(2) Direct that no new subjects be added to ongoing studies subject to this part;

(3) Terminate ongoing studies subject to this part when doing so would not endanger the subjects; or

(4) When the apparent noncompliance creates a significant threat to the rights and welfare of human subjects, notify relevant State and Federal regulatory agencies and other parties with a direct interest in the agency's action of the deficiencies in the operation of the IRB.

(c) The parent institution is presumed to be responsible for the operation of an IRB, and the Food and Drug Administration will ordinarily direct any administrative action under this subpart against the institution. However, depending on the evidence of responsibility for deficiencies, determined during the investigation, the Food and Drug Administration may restrict its administrative actions to the IRB or to a component of the parent institution determined to be responsible for formal designation of the IRB.

§ 56.121 Disqualification of an IRB or an institution.

(a) Whenever the IRB or the institution has failed to take adequate steps to correct the noncompliance stated in the letter sent by the agency under § 56.120(a), and the Commissioner of Food and Drugs determines that this noncompliance may justify the disqualification of the IRB or of the parent institution, the Commissioner will institute proceedings in accordance with the requirements for a regulatory hearing set forth in Part 16.

(b) The Commissioner may disqualify an IRB or the parent institution if the Commissioner determines that:

(1) The IRB has refused or repeatedly failed to comply with any of the regulations set forth in this part, and

(2) The noncompliance adversely affects the rights or welfare of the human subjects in a clinical investigation.

(c) If the Commissioner determines that disqualification is appropriate, the Commissioner will issue an order that explains the basis for the determination and that prescribes any actions to be taken with regard to ongoing clinical research conducted under the review of the IRB. The Food and Drug Administration will send notice of the disqualification to the IRB and the parent institution. Other parties with a direct interest, such as sponsors and clinical investigators, may also be sent a notice of the disqualification. In addition, the agency may elect to publish a notice of its action in the Federal Register.

(d) The Food and Drug Administration will not approve an application for a research permit for a clinical investigation that is to be under the review of a disqualified IRB or that is to be conducted at a disqualified institution, and it may refuse to consider in support of a marketing permit the data from a clinical investigation that was reviewed by a disqualified IRB as conducted at a disqualified institution, unless the IRB or the parent institution is reinstated as provided in § 56.123.

§ 56.122 Public disclosure of information regarding revocation.

A determination that the Food and Drug Administration has disqualified an institution and the administrative record regarding that determination are disclosable to the public under Part 20.

§ 56.123 Reinstatement of an IRB or an institution.

An IRB or an institution may be reinstated if the Commissioner determines, upon an evaluation of a written submission from the IRB or institution that explains the corrective action that the institution or IRB plans to take, that the IRB or institution has provided adequate assurance that it will operate in compliance with the standards set forth in this part. Notification of reinstatement shall be provided to all persons notified under § 56.121(c).

§ 56.124 Actions alternative or additional to disqualification.

Disqualification of an IRB or of an institution is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, through the Department of Justice institute any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and before, at the time of, or after, disqualification. The agency may also refer pertinent matters to another Federal, State, or local government agency for any action that that agency determines to be appropriate.

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

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AUTHORITY: Secs. 306, 402(a), 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 701(a), 706, 801, Pub. L. 717, 52 Stat. 1045-1046 as amended, 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 336, 342(a), 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360j, 371(a), 381); secs. 215, 351, 354-360F, Pub. L. 410, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n); 21 CFR 5.11.

SOURCE: 43 FR 60013, Dec. 22, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 58.1 Scope.

(a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 706, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987]

§ 58.3 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-392)).

(b) "Test article" means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act.

(c) "Control article" means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any article other than a test article, feed, or water that is administered to the test system in the course of a nonclinical laboratory study for the purpose of establishing a basis for comparison with the test article.

(d) "Nonclinical laboratory study" means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article.

(e) "Application for research or marketing permit" includes:

(1) A color additive petition, described in Part 71.

(2) A food additive petition, described in Parts 171 and 571.

(3) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for use, which use results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.35 and 570.35.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in § 180.1.

(5) An "investigational new drug application," described in Part 312 of this chapter.

(6) A "new drug application," described in Part 314.

(7) Data and information regarding an over-the-counter drug for human use, submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in Part 330.

(8) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in Parts 109 and 509.

(9) Data and information regarding an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for such drugs, described in § 314.300 of this chapter.

(10) A "Notice of Claimed Investigational Exemption for a New Animal Drug," described in Part 511.

(11) A "new animal drug application," described in Part 514.

(12) [Reserved]

(13) An "application for a biological product license," described in Part 601.

(14) An "application for an investigational device exemption," described in Part 812.

(15) An "Application for Premarket Approval of a Medical Device," described in section 515 of the act.

(16) A "Product Development Protocol for a Medical Device," described in section 515 of the act.

(17) Data and information regarding a medical device submitted as part of the procedures for classifying such devices, described in Part 860.

(18) Data and information regarding a medical device submitted as part of the procedures for establishing, amending, or repealing a performance standard for such devices, described in Part 861.

(19) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in Subpart D of Part 1003.

(20) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such product, described in section 358 of the Public Health Service Act.

(21) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard as described in § 1010.4.

(22) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from any electronic product performance standard, as described in § 1010.5.

(f) "Sponsor" means:

(1) A person who initiates and supports, by provision of financial or

other resources, a nonclinical laboratory study;

(2) A person who submits a nonclinical study to the Food and Drug Administration in support of an application for a research or marketing permit; or

(3) A testing facility, if it both initiates and actually conducts the study.

(g) "Testing facility" means a person who actually conducts a nonclinical laboratory study, i.e., actually uses the test article in a test system. "Testing facility" includes any establishment required to register under section 510 of the act that conducts nonclinical laboratory studies and any consulting laboratory described in section 704 of the act that conducts such studies. "Testing facility" encompasses only those operational units that are being or have been used to conduct nonclinical laboratory studies.

(h) "Person" includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

(i) "Test system" means any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study. "Test system" also includes appropriate groups or components of the system not treated with the test or control articles.

(j) "Specimen" means any material derived from a test system for examination or analysis.

(k) "Raw data" means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a nonclinical laboratory study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. "Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

(l) "Quality assurance unit" means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of nonclinical laboratory studies.

(m) "Study director" means the individual responsible for the overall conduct of a nonclinical laboratory study.

(n) "Batch" means a specific quantity or lot of a test or control article that has been characterized according to § 58.105(a).

(o) "Study initiation date" means the date the protocol is signed by the study director.

(p) "Study completion date" means the date the final report is signed by the study director.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 54 FR 9039, Mar. 3, 1989]

§ 58.10 Applicability to studies performed under grants and contracts.

When a sponsor conducting a nonclinical laboratory study intended to be submitted to or reviewed by the Food and Drug Administration utilizes the services of a consulting laboratory, contractor, or grantee to perform an analysis or other service, it shall notify the consulting laboratory, contractor, or grantee that the service is part of a nonclinical laboratory study that must be conducted in compliance with the provisions of this part.

§ 58.15 Inspection of a testing facility.

(a) A testing facility shall permit an authorized employee of the Food and Drug Administration, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies within the scope of this part. The records inspection and copying requirements shall not apply to quality assurance unit records of findings and problems, or to actions recommended and taken.

(b) The Food and Drug Administration will not consider a nonclinical laboratory study in support of an application for a research or marketing permit if the testing facility refuses to permit inspection. The determination that a nonclinical laboratory study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to the Food and Drug Administration.

Subpart B—Organization and Personnel

§ 58.29 Personnel.

(a) Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

(b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a nonclinical laboratory study.

(c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.

(d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems.

(e) Personnel engaged in a nonclinical laboratory study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and control articles.

(f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the nonclinical laboratory study shall be excluded from direct contact with test systems, test and control articles and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a nonclinical laboratory study.

§ 58.31 Testing facility management.

For each nonclinical laboratory study, testing facility management shall:

(a) Designate a study director as described in § 58.33, before the study is initiated.

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.

(c) Assure that there is a quality assurance unit as described in § 58.35.

(d) Assure that test and control articles or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

(e) Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

(f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

§ 58.33 Study director.

For each nonclinical laboratory study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control. The study director shall assure that:

(a) The protocol, including any change, is approved as provided by § 58.120 and is followed.

(b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.

(c) Unforeseen circumstances that may affect the quality and integrity of the nonclinical laboratory study are noted when they occur, and corrective action is taken and documented.

(d) Test systems are as specified in the protocol.

(e) All applicable good laboratory practice regulations are followed.

(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.

[43 FR 60013, Dec. 22, 1978; 44 FR 17657, Mar. 23, 1979]

§ 58.35 Quality assurance unit.

(a) A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study, the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

(b) The quality assurance unit shall:

(1) Maintain a copy of a master schedule sheet of all nonclinical laboratory studies conducted at the testing facility indexed by test article and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.

(2) Maintain copies of all protocols pertaining to all nonclinical laboratory studies for which the unit is responsible.

(3) Inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Any problems found during the course of an inspection which are likely to affect study integrity shall be brought to the attention of the study director and management immediately.

(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.

(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.

(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the nonclinical laboratory study.

(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.

(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees of the Food and Drug Administration.

(d) A designated representative of the Food and Drug Administration shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented, and followed-up in accordance with this paragraph.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0203)

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

Subpart C—Facilities

§ 58.41 General.

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of nonclinical laboratory studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

[52 FR 33780, Sept. 4, 1987]

§ 58.43 Animal care facilities.

(a) A testing facility shall have a sufficient number of animal rooms or areas, as needed, to assure proper: (1) Separation of species or test systems, (2) isolation of individual projects, (3) quarantine of animals, and (4) routine or specialized housing of animals.

(b) A testing facility shall have a number of animal rooms or areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test and control articles known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.

(c) Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory animal diseases. These areas shall provide effective isolation for the housing of animals either known or suspected of being diseased, or of being carriers of disease, from other animals.

(d) When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

§ 58.45 Animal supply facilities.

There shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

§ 58.47 Facilities for handling test and control articles.

(a) As necessary to prevent contamination or mixups, there shall be separate areas for:

(1) Receipt and storage of the test and control articles.

(2) Mixing of the test and control articles with a carrier, e.g., feed.

(3) Storage of the test and control article mixtures.

(b) Storage areas for the test and/or control article and test and control mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the articles and mixtures.

§ 58.49 Laboratory operation areas.

Separate laboratory space shall be provided, as needed, for the performance of the routine and specialized procedures required by nonclinical laboratory studies.

[52 FR 33780, Sept. 4, 1987]

§ 58.51 Specimen and data storage facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

Subpart D—Equipment

§ 58.61 Equipment design.

Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

[52 FR 33780, Sept. 4, 1987]

§ 58.63 Maintenance and calibration of equipment.

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated and/or standardized.

(b) The written standard operating procedures required under § 58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation.

(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0203)

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

Subpart E—Testing Facilities Operation

§ 58.81 Standard operating procedures.

(a) A testing facility shall have standard operating procedures in writing setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.

(b) Standard operating procedures shall be established for, but not limited to, the following:

(1) Animal room preparation.

(2) Animal care.

(3) Receipt, identification, storage, handling, mixing, and method of sampling of the test and control articles.

(4) Test system observations.

(5) Laboratory tests.

(6) Handling of animals found moribund or dead during study.

(7) Necropsy of animals or postmortem examination of animals.

(8) Collection and identification of specimens.

(9) Histopathology.

(10) Data handling, storage, and retrieval.

(11) Maintenance and calibration of equipment.

(12) Transfer, proper placement, and identification of animals.

(c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. Published literature may be used as a supplement to standard operating procedures.

(d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

§ 58.83 Reagents and solutions.

All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.

§ 58.90 Animal care.

(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals.

(b) All newly received animals from outside sources shall be isolated and their health status shall be evaluated in accordance with acceptable veterinary medical practice.

(c) At the initiation of a nonclinical laboratory study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary.

These animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorizations of treatment, description of treatment, and each date of treatment shall be documented and shall be retained.

(d) Warm-blooded animals, excluding suckling rodents, used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification (e.g., tattoo, toe clip, color code, ear tag, ear punch, etc.). All information needed to specifically identify each animal within an animal-housing unit shall appear on the outside of that unit.

(e) Animals of different species shall be housed in separate rooms when necessary. Animals of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to control or test articles or animal mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made.

(f) Animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals.

(g) Feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.

(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.

(i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0203)

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33780, Sept. 4, 1987]

Subpart F—Test and Control Articles

§ 58.105 Test and control article characterization.

(a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented. Methods of synthesis, fabrication, or derivation of the test and control articles shall be documented by the sponsor or the testing facility. In those cases where marketed products are used as control articles, such products will be characterized by their labeling.

(b) The stability of each test or control article shall be determined by the testing facility or by the sponsor either: (1) Before study initiation, or (2) concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch.

(c) Each storage container for a test or control article shall be labeled by name, chemical abstract number or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control article. Storage containers shall be assigned to a particular test article for the duration of the study.

(d) For studies of more than 4 weeks' duration, reserve samples from each batch of test and control articles shall be retained for the period of time provided by § 58.195.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0203)

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]

§ 58.107 Test and control article handling.

Procedures shall be established for a system for the handling of the test and control articles to ensure that:

(a) There is proper storage.

(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.

(c) Proper identification is maintained throughout the distribution process.

(d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.

§ 58.113 Mixtures of articles with carriers.

(a) For each test or control article that is mixed with a carrier, tests by appropriate analytical methods shall be conducted:

(1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test or control article in the mixture.

(2) To determine the stability of the test and control articles in the mixture as required by the conditions of the study either:

(i) Before study initiation, or

(ii) Concomitantly according to written standard operating procedures which provide for periodic analysis of the test and control articles in the mixture.

(b) [Reserved]

(c) Where any of the components of the test or control article carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.

[43 FR 60013, Dec. 22, 1978, as amended at 45 FR 24865, Apr. 11, 1980; 52 FR 33781, Sept. 4, 1987]

Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

§ 58.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain, as applicable, the following information:

(1) A descriptive title and statement of the purpose of the study.

(2) Identification of the test and control articles by name, chemical abstract number, or code number.

(3) The name of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(5) The procedure for identification of the test system.

(6) A description of the experimental design, including the methods for the control of bias.

(7) A description and/or identification of the diet used in the study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(8) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control article to be administered and the method and frequency of administration.

(9) The type and frequency of tests, analyses, and measurements to be made.

(10) The records to be maintained.

(11) The date of approval of the protocol by the sponsor and the dated signature of the study director.

(12) A statement of the proposed statistical methods to be used.

(b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0203)

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]

§ 58.130 Conduct of a nonclinical laboratory study.

(a) The nonclinical laboratory study shall be conducted in accordance with the protocol.

(b) The test systems shall be monitored in conformity with the protocol.

(c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.

(d) Records of gross findings for a specimen from postmortem observations should be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a nonclinical laboratory study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, shall be dated, and the responsible individual shall be identified.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0203)

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]

Subparts H-I—[Reserved]

Subpart J—Records and Reports

§ 58.185 Reporting of nonclinical laboratory study results.

(a) A final report shall be prepared for each nonclinical laboratory study and shall include, but not necessarily be limited to, the following:

(1) Name and address of the facility performing the study and the dates on which the study was initiated and completed.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Statistical methods employed for analyzing the data.

(4) The test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics.

(5) Stability of the test and control articles under the conditions of administration.

(6) A description of the methods used.

(7) A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.

(8) A description of the dosage, dosage regimen, route of administration, and duration.

(9) A description of all cirmcumstances that may have affected the quality or integrity of the data.

(10) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study.

(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study.

(13) The locations where all specimens, raw data, and the final report are to be stored.

(14) The statement prepared and signed by the quality assurance unit as described in § 58.35(b)(7).

(b) The final report shall be signed and dated by the study director.

(c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]

§ 58.190 Storage and retrieval of records and data.

(a) All raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study shall be retained.

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.

(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed to permit expedient retrieval.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0203)

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987]

§ 58.195 Retention of records.

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this chapter.

(b) Except as provided in paragraph (c) of this section, documentation records, raw data and specimens pertaining to a nonclinical laboratory study and required to be made by this part shall be retained in the archive(s) for whichever of the following periods is shortest:

(1) A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the nonclinical laboratory study were submitted, is approved by the Food and Drug Administration. This requirement does not apply to studies supporting investigational new drug applications (IND's) or applications for investigational device exemptions (IDE's), records of which shall be governed by the provisions of paragraph (b)(2) of this section.

(2) A period of at least 5 years following the date on which the results of the nonclinical laboratory study are submitted to the Food and Drug Administration in support of an application for a research or marketing permit.

(3) In other situations (e.g., where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

(c) Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material, which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraphs (a) and (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by § 58.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraphs (a) and (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by § 58.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraphs (a) and (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by § 58.63(b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.

(g) Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

(h) If a facility conducting nonclinical testing goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The Food and Drug Administration shall be notified in writing of such a transfer.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33781, Sept. 4, 1987; 54 FR 9039, Mar. 3, 1989]

Subpart K—Disqualification of Testing Facilities

§ 58.200 Purpose.

(a) The purposes of disqualification are: (1) To permit the exclusion from consideration of completed studies that were conducted by a testing facility which has failed to comply with the requirements of the good laboratory practice regulations until it can be adequately demonstrated that such noncompliance did not occur during, or did not affect the validity or acceptability of data generated by, a particular study; and (2) to exclude from consideration all studies completed after the date of disqualification until the facility can satisfy the Commissioner that it will conduct studies in compliance with such regulations.

(b) The determination that a nonclinical laboratory study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

§ 58.202 Grounds for disqualification.

The Commissioner may disqualify a testing facility upon finding all of the following:

(a) The testing facility failed to comply with one or more of the regulations set forth in this part (or any other regulations regarding such facilities in this chapter);

(b) The noncompliance adversely affected the validity of the nonclinical laboratory studies; and

(c) Other lesser regulatory actions (e.g., warnings or rejection of individual studies) have not been or will probably not be adequate to achieve compliance with the good laboratory practice regulations.

§ 58.204 Notice of and opportunity for hearing on proposed disqualification.

(a) Whenever the Commissioner has information indicating that grounds exist under § 58.202 which in his opinion justify disqualification of a testing facility, he may issue to the testing facility a written notice proposing that the facility be disqualified.

(b) A hearing on the disqualification shall be conducted in accordance with the requirements for a regulatory hearing set forth in Part 16 of this chapter.

§ 58.206 Final order on disqualification.

(a) If the Commissioner, after the regulatory hearing, or after the time for requesting a hearing expires without a request being made, upon an evaulation of the administrative record of the disqualification proceeding, makes the findings required in § 58.202, he shall issue a final order disqualifying the facility. Such order shall include a statement of the basis for that determination. Upon issuing a final order, the Commissioner shall notify (with a copy of the order) the testing facility of the action.

(b) If the Commissioner, after a regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, does not make the findings required in § 58.202, he shall issue a final order terminating the disqualification proceeding. Such order shall include a statement of the basis for that determination. Upon issuing a final order the Commissioner shall notify the testing facility and provide a copy of the order.

§ 58.210 Actions upon disqualification.

(a) Once a testing facility has been disqualified, each application for a research or marketing permit, whether approved or not, containing or relying upon any nonclinical laboratory study conducted by the disqualified testing facility may be examined to determine whether such study was or would be essential to a decision. If it is determined that a study was or would be essential, the Food and Drug Administration shall also determine whether the study is acceptable, notwithstanding the disqualification of the facility. Any study done by a testing facility before or after disqualification may be presumed to be unacceptable, and the person relying on the study may be required to establish that the study was not affected by the circumstances that led to the disqualification, e.g., by submitting validating information. If the study is then determined to be unacceptable, such data such be eliminated from consideration in support of the application; and such elimination may serve as new information justifying the termination or withdrawal of approval of the application.

(b) No nonclinical laboratory study begun by a testing facility after the date of the facility's disqualification shall be considered in support of any application for a research or marketing permit, unless the facility has been reinstated under § 58.219. The determination that a study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

§ 58.213 Public disclosure of information regarding disqualification.

(a) Upon issuance of a final order disqualifying a testing facility under § 58.206(a), the Commissioner may notify all or any interested persons. Such notice may be given at the discretion of the Commissioner whenever he believes that such disclosure would further the public interest or would promote compliance with the good laboratory practice regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under § 58.206(a) and shall state that the disqualification constitutes a determination by the Food and Drug Administration that nonclinical laboratory studies performed by the facility will not be considered by the Food and Drug Administration in support of any application for a research or marketing permit. If such notice is sent to another Federal Government agency, the Food and Drug Administration will recommend that the agency also consider whether or not it should accept nonclinical laboratory studies performed by the testing facility. If such notice is sent to any other person, it shall state that it is given because of the relationship between the testing facility and the person being notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified.

(b) A determination that a testing facility has been disqualified and the administrative record regarding such determination are disclosable to the public under Part 20 of this chapter.

§ 58.215 Alternative or additional actions to disqualification.

(a) Disqualification of a testing facility under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, institute against a testing facility and/or against the sponsor of a nonclinical laboratory study that has been submitted to the Food and Drug Administration any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and prior to, simultaneously with, or subsequent to, disqualification. The Food and Drug Administration may also refer the matter to another Federal, State, or local government law enforcement or regulatory agency for such action as that agency deems appropriate.

(b) The Food and Drug Administration may refuse to consider any particular nonclinical laboratory study in support of an application for a research or marketing permit, if it finds that the study was not conducted in accordance with the good laboratory practice regulations set forth in this part, without disqualifying the testing facility that conducted the study or undertaking other regulatory action.

§ 58.217 Suspension or termination of a testing facility by a sponsor.

Termination of a testing facility by a sponsor is independent of, and neither in lieu of nor a precondition to, proceedings or actions authorized by this subpart. If a sponsor terminates or suspends a testing facility from further participation in a nonclinical laboratory study that is being conducted as part of any application for a research or marketing permit that has been submitted to any Center of the Food and Drug Administration (whether approved or not), it shall notify that Center in writing within 15 working days of the action; the notice shall include a statement of the reasons for such action. Suspension or termination of a testing facility by a sponsor does not relieve it of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

[43 FR FR 60013, Dec. 22, 1978 as amended at 50 FR 8995, Mar. 6, 1985]

§ 58.219 Reinstatement of a disqualified testing facility.

A testing facility that has been disqualified may be reinstated as an acceptable source of nonclinical laboratory studies to be submitted to the Food and Drug Administration if the Commissioner determines, upon an evaluation of the submission of the testing facility, that the facility can adequately assure that it will conduct future nonclinical laboratory studies in compliance with the good laboratory practice regulations set forth in this part and, if any studies are currently being conducted, that the quality and integrity of such studies have not been seriously compromised. A disqualified testing facility that wishes to be so reinstated shall present in writing to the Commissioner reasons why it believes it should be reinstated and a detailed description of the corrective actions it has taken or intends to take to assure that the acts or omissions which led to its disqualification will not recur. The Commissioner may condition reinstatement upon the testing facility being found in compliance with the good laboratory practice regulations upon an inspection. If a testing facility is reinstated, the Commissioner shall so notify the testing facility and all organizations and persons who were notified, under § 58.213 of the disqualification of the testing facility. A determination that a testing facility has been reinstated is disclosable to the public under Part 20 of this chapter.

PART 60—PATENT TERM RESTORATION

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AUTHORITY: Secs. 409, 505, 507, 515, 520, 701, 706 (21 U.S.C. 348, 353, 355, 357, 360e, 360j, 371, 376); sec. 351 (42 U.S.C. 262); sec. 201 (35 U.S.C. 156).

Source: 53 FR 7305, Mar. 7, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 60.1 Scope.

(a) This part sets forth procedures and requirements for the Food and Drug Administration's review of applications for the extension of the term of certain patents under 35 U.S.C. 156. Patent term restoration is available for certain patents related to human drug products (as defined in 35 U.S.C. 156(f)(2)), and to medical devices, food additives, or color additives subject to regulation under the Federal Food, Drug, and Cosmetic Act. Food and Drug Administration actions in this area include:

(1) Assisting the United States Patent and Trademark Office in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to the Food and Drug Administration's regulatory review period determinations; and

(4) Conducting hearings to review initial Food and Drug Administration findings on due diligence challenges.

(b) References in this part to the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 60.2 Purpose.

(a) The purpose of this part is to establish a thorough yet efficient process for the Food and Drug Administration review of patent term restoration applications. To achieve this purpose, the regulations are intended to:

(1) Facilitate determinations of patent term restoration eligibility and regulatory review period length, and

(2) Ensure that parties interested in due diligence challenges will have an opportunity to participate in that process, including informal hearings.

(b) The regulations are intended to complement those promulgated by the United States Patent and Trademark Office to implement those parts of the law which are under that agency's jurisdiction. These regulations shall be construed in light of these objectives.

§ 60.3 Definitions.

(a) The definitions contained in 35 U.S.C. 156 apply to those terms when used in this part.

(b) The following definitions of terms apply to this part:

(1) The term "Act" means the Federal Food, Drug, and Cosmetic Act (secs. 201-901, 52 Stat. 1040 et seq. as amended (21 U.S.C. 301-392)).

(2) "Active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(3) "Applicant" means any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking patent term restoration.

(4) "Application" means an application for patent term restoration submitted under 35 U.S.C. 156.

(5) "Clinical investigation or study" means any experiment that involves a test article and one or more human subjects and that is either subject to requirements for prior submission to the Food and Drug Administration under section 505(i), 507(d), or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to the requirements for prior submission to FDA under those sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be submitted later to, or held for inspection by, FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of Part 58 regarding nonclinical laboratory studies.

(6) "Color additive" means any substance that meets the definition in sec-

tion 201(t) of the Act and which is subject to premarketing approval under section 706 of the Act.

(7) "Due diligence petition" means a petition submitted under § 60.30(a).

(8) "FDA" means the Food and Drug Administration.

(9) "Food additive" means any substance that meets the definition in section 201(s) of the Act and which is subject to premarketing approval under section 409 of the Act.

(10) "Human drug product" means the active ingredient of a new drug, antibiotic drug, or human biologic product (as those terms are used in the Act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.

(11) "Marketing applicant" means any person who submits an application for premarketing approval by FDA under:

(i) Section 505(b) or 507 of the Act or section 351 of the Public Health Service Act (human drug products);

(ii) Section 515 of the Act (medical devices); or

(iii) Section 409 or 706 of the Act (food and color additives).

(12) "Marketing application" means an application for:

(i) Human drug products submitted under section 505(b) or 507 of the Act or section 351 of the Public Health Service Act;

(ii) Medical devices submitted under section 515 of the Act; or

(iii) Food and color additives submitted under section 409 or 706 of the Act.

(13) "Medical device" means any article that meets the definition in section 201(h) of the Act and which is subject to premarketing approval under section 515 of the Act.

(14) "Product" means a human drug product, medical device, food additive, or color additive, as those terms are defined in this section.

(15) "PTO" means the United States Patent and Trademark Office.

Subpart B—Eligibility Assistance

§ 60.10 FDA assistance on eligibility.

(a) Upon written request from PTO, FDA will assist PTO in determining whether a patent related to a product is eligible for, patent term restoration by:

(1) Verifying whether the product was subject to a regulatory review period before its commercial marketing or use;

(2) Determining whether the permission for commercial marketing or use of the product after the regulatory review period is the first permitted commercial marketing or use of the product either:

(i) Under the provision of law under which the regulatory review period occurred; or

(ii) Under the process claimed in the patent when the patent claims a method of manufacturing the product that primarily uses recombinant deoxyribonucleic acid (DNA) technology in the manufacture of the product;

(3) Informing PTO whether the patent term restoration application was submitted within 60 days after the product was approved for marketing or use; and

(4) Providing PTO with any other information relevant to PTO's determination of whether a patent related to a product is eligible for patent term restoration.

(b) FDA will notify PTO of its findings in writing, send a copy of this notification to the applicant, and file a copy of the notification in the docket established for the application in FDA's Dockets Management Branch (HFA-305), Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

Subpart C—Regulatory Review Period Determinations

§ 60.20 FDA action on regulatory review period determinations.

(a) FDA will consult its records and experts to verify the dates contained in the application and to determine the length of the product's regulatory review period under § 60.22. The application shall contain information relevant to the determination of the regulatory review period as stated in the "Guidelines for Extension of Patent Term Under 35 U.S.C. 156" published on October 9, 1984, in PTO's *Official Gazette* and as required by 37 CFR Chapter I.

(b) After determining the length of the regulatory review period, FDA will notify PTO in writing of its determination, send a copy of this determination to the applicant, and file a copy of the determination in the docket established for the application in FDA's Dockets Management Branch (HFA-305), Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

(c) FDA will also publish the regulatory review period determination in the FEDERAL REGISTER. The notice will include the following:

(1) The name of the applicant;

(2) The trade name and generic name (if applicable) of the product;

(3) The number of the patent for which an extension of the term is sought;

(4) The approved indications or uses for the product;

(5) An explanation of any discrepancies between the dates in the application and FDA records;

(6) Where appropriate, an explanation that FDA has no record in which to review the date(s) contained in the application; and

(7) The regulatory review period determination, including a statement of the length of the testing and approval phases and the dates used in calculating each phase.

§ 60.22 Regulatory review period determinations.

In determining a product's regulatory review period, which consists of the sum of the lengths of a testing phase and an approval phase, FDA will review the information in each application using the following definitions of the testing phase and the approval phase for that class of products.

(a) For human drugs:

(1) The testing phase begins on the date an exemption under section 505(i) or 507(d) of the Act becomes effective for the approved human drug product and ends on the date a marketing application under section 351 of the Public Health Service Act or section 505 or 507 of the Act is initially submitted to FDA, and

(2) The approval phase begins on the date a marketing application under section 351 of the Public Health Service Act or section 505(b) or 507 of the Act is initially submitted to FDA and ends on the date the application is approved.

(b) For food and color additives:

(1) The testing phase begins on the date a major health or environmental effects test is begun and ends on the date a petition relying on the test and requesting the issuance of a regulation for use of the additive under section 409 or 706 of the Act is initially submitted to FDA. For purposes of this part, a "major health or environmental" effects test may be any test which:

(i) Is reasonably related to the evaluation of the product's health effects, environmental effects, or both;

(ii) Produces data necessary for marketing approval; and

(iii) Is conducted over a period of not less than 6 months-duration, excluding time required to analyze or evaluate test results.

(2) The approval phase begins on the date a petition requesting the issuance of a regulation for use of the additive under section 409 or 706 of the Act is initially submitted to FDA and ends upon whichever of the following occurs last:

(i) The regulation for the additive becomes effective; or

(ii) Objections filed against the regulation that result in a stay of effectiveness are resolved and commercial marketing is permitted; or

(iii) Proceedings resulting from objections to the regulation, after commercial marketing has been permitted and later stayed pending resolution of the proceedings, are finally resolved and commercial marketing is permitted.

(c) For medical devices:

(1) The testing phase begins on the date a clinical investigation on humans is begun and ends on the date an application for premarket approval of the device or a notice of completion of a product development protocol is initially submitted under section 515

of the Act. For purposes of this part, a clinical investigation is considered to begin on whichever of the following dates applies:

(i) If an investigational device exemption (IDE) under section 520(g) of the Act is required, the effective date of the exemption.

(ii) If an IDE is not required, but institutional review board (IRB) approval under section 520(g)(3) of the Act is required, the IRB approval date.

(iii) If neither an IDE nor IRB approval is required, the date on which the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device.

(2) The approval phase either:

(i) Begins on the date an application for premarket approval of the device is initially submitted under section 515 of the Act and ends on the date the application is approved; or

(ii) Begins on the date a notice of completion of a product development protocol is initially submitted under section 515 of the Act and ends on the date the protocol is declared to be completed.

(d) For purposes of determining the regulatory review period for any product, a marketing application, a notice of completion of a product development protocol, or a petition is "initially submitted" on the date it contains sufficient information to allow FDA to commence review of the application. A marketing application, a notice of completion of a product development protocol, or a petition is "approved" on the date FDA sends the applicant a letter informing it of the approval or, by order declares a product development protocol to be completed, or, in the case of food and color additives, on the effective date of the final rule listing the additive for use as published in the FEDERAL REGISTER.

§ 60.24 Revision of regulatory review period determinations.

(a) Any person may request a revision of the regulatory review period determination within 60 days after its initial publication in the FEDERAL REGISTER. The request shall be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. The request shall specify the following:

(1) The type of action requested;

(2) The identity of the product;

(3) The identity of the applicant;

(4) The FDA docket number; and

(5) The basis for the request for revision, including any documentary evidence.

(b) Unless the applicant is the person requesting the revision, the applicant shall respond to the request within 15 days. In responding to the request, the applicant may submit information which is relevant to the events during the regulatory review period but which was not included in the original patent term restoration application. A request for a revision is not equivalent to a due diligence petition under § 60.30 or a request for a hearing under § 60.40. If no response is submitted, FDA will decide the matter on the basis of the information in the patent term restoration application, request for revision, and FDA records.

(c) FDA shall apply the provisions of § 60.22 in considering the request for a revision of the regulatory review period determination. If FDA revises its prior determination, FDA will notify PTO of the revision, send a copy of this notification to the applicant, and publish the revision in the FEDERAL REGISTER, including a statement giving the reasons for the revision.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0233)

§ 60.26 Final action on regulatory review period determinations.

(a) FDA will consider a regulatory review period determination to be final upon expiration of the 180-day period for filing a due diligence petition under § 60.30 unless FDA receives:

(1) New information from PTO records, FDA records, or FDA centers that affects the regulatory review period determination;

(2) A request under § 60.24 for revision of the regulatory review period determination;

(3) A due diligence petition filed under § 60.30; or

(4) A request for a hearing filed under § 60.40.

(b) FDA will notify PTO that the regulatory review period determination is final upon:

(1) The expiration of the 180-day period for filing a due diligence petition; or

(2) If FDA has received a request for a revision, a due diligence petition, or a request for a hearing, upon resolution of the request for a revision, the petition, or the hearing, whichever is later. FDA will send a copy of the notification to the applicant and file a copy of the notification in the docket established for the application in FDA's Dockets Management Branch (HFA-305), Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

§ 60.28 Time frame for determining regulatory review periods.

(a) FDA will determine the regulatory review period for a product within 30 days of the receipt of a written request from PTO for such a determination and a copy of the patent term restoration application.

(b) FDA may extend the 30-day period if:

(1) A related FDA action that may affect the regulatory review period determination is pending; or

(2) PTO requests that FDA temporarily suspend the determination process; or

(3) PTO or FDA receives new information about the product that warrants an extension of the time required for the determination of the regulatory review period.

(c) This section does not apply to applications withdrawn by the applicant or applications that PTO determines are ineligible for patent term restoration.

Subpart D—Due Diligence Petitions

§ 60.30 Filing, format, and content of petitions.

(a) Any person may file a petition with FDA, no later than 180 days after the publication of a regulatory review period determination under § 60.20, that challenges FDA's determination by alleging that the applicant for patent term restoration did not act with due diligence in seeking FDA approval of the product during the regulatory review period.

(b) The petition shall be filed in accordance with § 10.20, under the docket number of the Federal Register notice of the agency's regulatory review period determination, and shall be in the format specified in § 10.30. The petition shall contain the information specified in § 10.30 and any additional information required by this subpart. If any provision of § 10.20 or § 10.30 is inconsistent with any provision of this part, FDA will consider the petition in accordance with this part.

(c) The petition shall claim that the applicant did not act with due diligence during some part of the regulatory review period and shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.

(d) The petition shall contain a certification that the petitioner has served a true and complete copy of the petition upon the applicant by certified or registered mail (return receipt requested) or by personal delivery.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0233)

§ 60.32 Applicant response to petition.

(a) The applicant shall file with FDA a written response to the petition no later than 30 days after the applicant's receipt of a copy of the petition.

(b) The applicant's response may present additional facts and circumstances to address the assertions in the petition, but shall be limited to the issue of whether the applicant acted with due diligence during the regulatory review period. The applicant's response may include documents that were not in the original patent extension application.

(c) If the applicant does not respond to the petition, FDA will decide the matter on the basis of the information submitted in the patent term restoration application, due diligence petition, and FDA records.

§ 60.34 FDA action on petitions.

(a) Within 90 days after FDA receives a petition filed under § 60.30(a), the agency will either deny the petition under paragraph (b) or (c) of this section or investigate and determine under § 60.36 whether the applicant acted with due diligence during the regulatory review period. FDA will publish its due diligence determination in the FEDERAL REGISTER, notify PTO of the due diligence determination in writing, and send copies of the notice to PTO, the applicant, and the petitioner.

(b) FDA may deny a due diligence petition without considering the merits of the petition if:

(1) The petition is not filed in accordance with § 60.30;

(2) The petition is not filed in accordance with § 10.20;

(3) The petition does not contain the information required by § 10.30;

(4) The petition fails to contain information or allegations upon which it may reasonably be determined that the applicant did not act with due diligence during the applicable regulatory review period; or

(5) The petition fails to allege a sufficient total amount of time during which the applicant did not exercise due diligence such that, even if the petition were granted, the petition would not affect the maximum patent extension the applicant sought in the application.

§ 60.36 Standard of due diligence.

(a) In determining the due diligence of an applicant, FDA will examine the facts and circumstances of the applicant's actions during the regulatory review period to determine whether the applicant exhibited that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period. FDA will take into consideration all relevant factors, such as the amount of time between the approval of an investigational exemption or research permit and the commencement of a clinical investigation and the amount of time required to conduct a clinical investigation.

(b) For purposes of this part, the actions of the marketing applicant shall be imputed to the applicant for patent term restoration. The actions of an agent, attorney, contractor, employee, licensee, or predecessor in interest of the marketing applicant or applicant for patent term restoration shall be imputed to the applicant for patent term restoration.

Subpart E—Due Diligence Hearings

§ 60.40 Request for hearing.

(a) Any person may request, not later than 60 days after the publication under § 60.34(a) of FDA's due diligence determination, that FDA conduct an informal hearing on the due diligence determination.

(b) The request for a hearing under this section shall:

(1) Be sent by mail, personal delivery, or any other mode of written communication to the Dockets Management Branch and filed under the relevant product file;

(2) Specify the facts and the action that are the subject of the hearing;

(3) Provide the name and address of the person requesting the hearing; and

(4) Certify that the requesting party has served a true and complete copy of the request upon the petitioner and the applicant by certified or registered mail (return receipt requested) or by personal delivery.

(c) The request shall state whether the requesting party seeks a hearing within 30 days or 60 days of FDA's receipt of the request.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0233)

§ 60.42 Notice of hearing.

Ten days before the hearing, FDA will notify the requesting party, the applicant, and the petitioner, orally or in writing, of the date, time, and location of the hearing. The agency will provide the requesting party, the applicant, and the petitioner with an opportunity to participate as a party in the hearing.

§ 60.44 Hearing procedures.

The due diligence hearing shall be conducted in accordance with this part, supplemented by the nonconflicting procedures in Part 16. During the due diligence hearing, the applicant and the petitioner shall enjoy all the rights and privileges accorded a person requesting a hearing under Part 16. The standard of due diligence set forth in § 60.36 will apply in the due diligence hearing. The party requesting the due diligence hearing shall have the burden of proof at the hearing.

§ 60.46 Administrative decision.

Within 30 days after the completion of the due diligence hearing, the Commissioner will affirm or revise the determination made under § 60.34(a) and will publish the due diligence redetermination in the FEDERAL REGISTER, notify PTO of the redetermination, and send copies of the notice to PTO and to the requesting party, the applicant, and the petitioner.

PART 70—COLOR ADDITIVES

Subpart A—General Provisions

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AUTHORITY: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376).

SOURCE: 42 FR 15636, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 70.3 Definitions.

(a) "Secretary" means the Secretary of Health and Human Services.

(b) "Department" means the Department of Health and Human Services.

(c) "Commissioner" means the Commissioner of Food and Drugs.

(d) "Act" means the Federal Food, Drug, and Cosmetic Act as amended.

(e) "Color Certification Branch" means the unit established within the Food and Drug Administration located in the Bureau of Foods, charged with the responsibility for the mechanics of the certification procedure hereinafter described, and including the examination of samples of color additives subject to certification.

(f) A "color additive" is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the transmittal of the color to the contents of the package or any part thereof. Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as "color additives"; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a "color additive." Food ingredients as authorized by a definitions and standard of identity prescribed by regulations pursuant to section 401 of the act are "color additives," where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such ingredient has nutritive or other functions in addition to the property of imparting color. An ingested drug the intended function of which is to impart color to the human body is a "color additive." For the purposes of this part, the term "color" includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not "color additives."

(g) For a material otherwise meeting the definition of "color additive" to be exempt from section 706 of the act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)

(h) The exemption that applies to a pesticide chemical, soil or plant nutrient, or other agricultural chemical, where its coloring effect results solely from its aiding, retarding, or otherwise affecting directly or indirectly, the growth or other natural physiological processes of produce of the soil, applies only to color developed in such product through natural physiological processes such as enzymatic action. If the pesticide chemical, soil or plant nutrient, or other agricultural chemical itself acts as a color or carries as an ingredient a color, and because of this property colors the produce of the soil, it is a "color additive" and is not exempt.

(i) "Safe" means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

(j) The term "straight color" means a color additive listed in Parts 73, 74, and 81 of this chapter, and includes lakes and such substances as are permitted by the specifications for such color.

(k) The term "mixture" means a color additive made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(l) The term "lake" means a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process.

(m) The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

(n) The term "substratum" means the substance on which the pure color in a lake is extended.

(o) The term "pure color" means the color contained in a color additive, exclusive of any intermediate or other component, or of any diluent or substratum contained therein.

(p) The term "batch" means a homogeneous lot of color additive or color additive mixture produced by an identified production operation, which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(q) The term "batch number" means the number assigned to a batch by the person who requests certification thereof.

(r) The term "lot number" means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(s) The term "area of the eye" means the area enclosed with in the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(t) The term "package" means the immediate container in which a color additive or color additive mixture has been packed for shipment or delivery. If the package is then packed in a shipping carton or other protective container, such container shall not be considered to be the immediate container. In the case of color additive mixtures for household use containing less than 15 percent pure color, when two or more containers of 3 ounces each or less, each containing a different color, are distributed as a unit, the immediate container for such unit shall be considered to be the package as defined in this section.

(u) The "hair dye" exemption in section 601(a) of the act applies to coal tar hair dyes intended for use in altering the color of the hair and which are, or which bear or contain, color additives derived from coal tar with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. The exemption does not apply to coloring ingredients in hair dyes not derived from coal tar, and it does not extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditions, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetic that alter the color of the hair.

(v) The terms "externally applied drugs" and "externally applied cosmetics" mean drugs or cosmetics applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

§ 70.5 General restrictions on use of color additives.

(a) *Color additives for use in the area of the eye.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in the area of the eye unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use in the area of the eye, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under Parts 73, 74, and 81 of this chapter, even though such color additive is certified and/or listed for other uses.

(b) *Color additives for use in injections.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use in injections unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use in injections, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under Parts 73, 74, and 81 of this chapter, even though such color additive is certified and/or listed for other uses.

(c) *Color additives for use in surgical sutures.* No listing or certification of a color additive shall be considered to authorize the use of any such color additive in any article intended for use as a surgical suture unless such listing or certification of such color additive specifically provides for such use. Any color additive used in or on any article intended for use as a surgical suture, the listing or certification of which color additive does not provide for such use, shall be considered to be a color additive not listed under Parts 73, 74, and 81 of this chapter, even though such color additive is certified and/or listed for other uses.

§ 70.10 Color additives in standardized foods, new drugs, and antibiotics.

(a) *Standardized foods.* (1) Where a petition is received for issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a color additive in the standardized food, the provisions of the regulations in Part 71 of this chapter shall apply with respect to the information that must be submitted with respect to the safety of the color additive (if such information has not previously been submitted and safety of the color additive for the intended use has not been already established), and the petition must show also that the use of the color additive in the standardized food would be in conformance with section 401 of the act or with the terms of a temporary permit issued under § 130.17 of this chapter.

(2) If a petition for a definition and standard of identity contains a proposal for a color additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a color additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in Part 71 of this chapter.

(3) A regulation will not be issued allowing the use of a color additive in a food for which a definition and standard of identity is established, unless its issuance is in conformance with section 401 of the act or with the terms of a temporary permit issued under § 130.17 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the color additive regulation will be conditioned on such compliance and will expire with the expiration of the temporary permit.

(b) *New drugs and antibiotics.* (1) Where an application for a new drug or for certification of an antibiotic drug is received and this application proposes, for coloring purposes only, the inclusion of a color additive, the provisions of the regulations in Part 71 of this chapter shall apply with respect to the information that must be submitted about the safety of the color additive, if such information has not previously been submitted and safety of the color additive for the intended use has not already been established.

(2) If an application for a new drug or certification of an antibiotic drug inferentially contains a proposal for a color additive regulation, and the applicant fails to designate it as such, the Commissioner, upon determining that the application includes a proposal for a color additive regulation, shall so notify the applicant and shall thereafter proceed in accordance with the regulations in Part 71 of this chapter.

(3) Where a petition for a color additive must be filed in accordance with paragraph (b)(2) of this section, the date of filing of the color additive petition shall be considered as the date of filing of the new-drug application or the request for certification of the antibiotic drug.

§ 70.11 Related substances.

(a) Different color additives may cause similar or related pharmacological or biological effects, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(b) Food additives may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered as having additive toxic effects.

(c) Pesticide chemicals may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(d) In establishing tolerances for color additives, the Commissioner will take into consideration, among other things, the amount of any common component permitted in other color additives, in food additives, and in pesticide chemical residues as well as the similar biological activity (such as cholinesterase inhibition) produced by such substance.

§ 70.19 Fees for listing.

(a) Each petition for the listing of a color additive shall be accompanied by a deposit of $3,000.00 if the proposal is for listing the color additive for use generally in or on foods, in or on drugs, and in or on cosmetics.

(b) If the petition for the listing is for use in or on foods only, the deposit shall be $3,000.00.

(c) If the petition for the listing is for use in or on drugs and/or cosmetics only, the deposit shall be $2,600.00.

(d) The provisions of paragraphs (a), (b), and (c) of this section shall be applicable, whether or not the proposal contemplates any tolerances, limitations, or other restrictions placed upon the use of the color additive.

(e) If a petition proposing the issuance of a regulation is withdrawn before it is finally accepted for filing, the deposit, less a $600.00 fee for clerical handling and administrative and technical review, shall be returned to the petitioner.

(f) If a petition proposing the issuance of a regulation is withdrawn within 30 days after filing, the deposit, less $1,800.00 if the petition is covered by paragraph (a) or (b) of this section, and less $1,600.00, if the petition is covered by paragraph (c) of this section, shall be returned to the petitioner.

(g) When a petition is withdrawn after filing and resubmitted within 6 months, it shall be accompanied by a deposit of $1,800.00 for a petition filed under paragraph (a) or (b) of this section, and $1,600.00 for a petition filed under paragraph (c) of this section. If a petition is resubmitted after 6 months, it shall be accompanied by the deposit that would be required if it were being submitted for the first time.

(h) When the resubmission pertains to a petition that had been withdrawn before acceptance for filing, a new advance deposit shall be made in full as prescribed in paragraph (a), (b), or (c) of this section.

(i) After a color additive has been listed, any request for an amendment or additional tolerance shall be accompanied by a deposit of $1,800.00 for use in the items specified in paragraphs (a) and (b) of this section, or $1,600.00 for use in items specified in paragraph (c) of this section.

(j) The fee for services in listing a diluent under § 80.35 for use in color additive mixtures shall be $250.00.

(k) Objections and request for public hearing under section 706(d) of the act or section 203(d)(2)(C) of Pub. L. 86-618 (74 Stat. 404; 21 U.S.C. 376, note) shall be accompanied by a filing fee of $250.00.

(l) In the event of a referral of a petition under this section to an advisory committee, all costs related thereto (including personal compensation of committee members, travel materials, and other costs) shall be borne by the person or organization requesting the referral, such costs to be assessed on the basis of actual cost to the Government: *Provided,* That the compensation of such costs shall include personal compensation of advisory committee members at a rate not to exceed $75.00 per member per day.

(m) In the case of requests of referrals to advisory committees, a special advance deposit shall be made in the amount of $2,500.00. Where required, further advance in increments of $2,500.00 each shall be made upon request of the Commissioner of Food and Drugs. All deposits for referrals to advisory committees in excess of actual expenses shall be refunded to the depositor.

(n) All requests for pharmacological or other scientific studies shall be accompanied by an advance deposit of $5,000.00. Further advance deposits shall be made upon request of the Commissioner of Food and Drugs when necessary to prevent arrears in such cost. Any deposits in excess of actual expenses will be refunded to the depositor. If a request is denied the advance deposit will be refunded less such costs as are incurred for review of the request.

(o) The person who files a petition for judicial review of an order under section 706(d) of the act shall pay the costs of preparing a transcript of the record on which the order is based.

(p) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft or certified check drawn to the order of the Food and Drug Administration, collectable at par at Washington, DC All deposits and fees shall be forwarded to the Division of Food and Color Additives, HFF-330, Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States for deposit in the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(q) The Commissioner of Food and Drugs may waive or refund such fees in whole or in part when in his judgment such action will promote the public interest.

(r) Any person who believes that payment of these fees will work a hardship on him may petition the Commissioner of Food and Drugs to waive or refund the fees.

Subpart B—Packaging and Labeling

§ 70.20 Packaging requirements for straight colors (other than hair dyes).

Straight colors shall be packaged in containers which prevent changes in composition. Packages shall be sealed so that they cannot be opened without breaking the seal. An unavoidable change in moisture content caused by the ordinary and customary exposure that occurs in good storage, packing, and distribution practice is not considered a change in composition. If the packaging material is a food additive it shall be authorized by an appropriate regulation in Parts 170 through 189 of this chapter.

§ 70.25 Labeling requirements for color additives (other than hair dyes).

(a) *General labeling requirements.* All color additives shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by this part and Parts 71, 73, 74, 80, and 81 of this chapter. In addition to all other information required by the act, labels for color additives, except those in a form suitable for coloring the human body, shall state:

(1) The name of the straight color or the name of each ingredient comprising the color additive, if it is a mixture.

(2) A statement indicating general limitations for the use of the color additive, such as "for food use only"; "for food, drug, and cosmetic use"; "for use in drugs for external application only."

(3) Where regulations issued impose quantitative limitations for a general or specific use of a straight color, the amount of each such straight color in terms of weight per unit/volume or percent by weight.

(4) An expiration date if stability data require it.

(b) *Special labeling for color additives with tolerances.* Where tolerances are imposed for a general or specific use of a color additive, the label shall in addition provide directions for use of the color additive which if followed will preclude the food, drug, or cosmetic to which it is added from containing an amount of the color additive in excess of the tolerance.

(c) *Special labeling for color additives with other limitations.* If use of the color additive is subject to other limitations prescribed in this part, such limitations shall be stated on the label of the color additive by a plain and conspicuous statement. Examples of such limitation statements are: "Do not use in products used in the area of the eye"; "Do not use for coloring drugs for injection."

(d) *Special labeling for color additives not exempt from certification.* Color additives not exempt from the certification procedures shall in addition include in the labeling the lot number assigned by the Color Certification Branch, except that in the case of any mixture for household use which contains not more than 15 percent of pure color and which is in packages containing not more than 3 ounces there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the Food and Drug Administration written notice that such code number will be used in lieu of the lot number.

Subpart C—Safety Evaluation

§ 70.40 Safety factors to be considered.

In accordance with section 706(b)(5)(A)(iii) of the act, the following safety factor will be applied in determining whether the proposed use of a color additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor of 100 to 1 will be used in applying animal experimentation data to man; that is, a color additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum no-effect level for the most susceptible experimental animals tested. The various species of experimental animals used in the tests shall conform to good pharmacological practice.

§ 70.42 Criteria for evaluating the safety of color additives.

(a) In deciding whether a petition is complete and suitable for filing and in reaching a decision on any petition filed, the Commissioner will apply the "safe-for-use" principle. This will require the presentation of all needed scientific data in support of a proposed listing to assure that each listed color additive will be safe for its intended use or uses in or on food, drugs, or cosmetics. The Commissioner may list a color additive for use generally in or on food, in or on drugs, or in or on cosmetics when he finds from the data presented that such additive is suitable and may safely be employed for such general use; he may list an additive only for more limited use or uses for which it is proven suitable and may safely be employed; and he is authorized to prescribe broadly the conditions under which the additive may be safely employed for such use or uses. This may allow the use of a particular dye, pigment, or other substance with certain diluents, but not with others, or at a higher concentration with some than with others.

(b) The safety for external color additives will normally be determined by tests for acute oral toxicity, primary irritation, sensitization, subacute dermal toxicity on intact and abraded skin, and carcinogenicity by skin application. The Commissioner may waive any of such tests if data before him otherwise establish that such test is not required to determine safety for the use proposed.

(c) Upon written request describing the proposed use of a color additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a color additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 70.45 Allocation of color additives.

Whenever, in the consideration of a petition or a proposal to list a color additive or to alter an existing listing, the data before the Commissioner fail to show that it would be safe to list the color additive for all the uses proposed or at the levels proposed, the Commissioner will notify the petitioner and other interested persons by publication in the FEDERAL REGISTER that it is necessary to allocate the safe tolerance for the straight color in the color additive among the competing needs. This notice shall call for the presentation of data by all interested persons on which the allocation can be made in accordance with section 706(b)(8) of the act. The time for acting upon the petition shall be stayed until such data are presented, whereupon the time limits shall begin to run anew. As promptly as possible after presentation of the data, the Commissioner will, by order, announce the allocation and the tolerance limitations.

§ 70.50 Application of the cancer clause of section 706 of the act.

(a) *Color additives that may be ingested.* Whenever (1) the scientific data before the Commissioner (either the reports from the scientific literature or the results of biological testing) suggest the possibility that the color additive including its components or impurities has induced cancer when ingested by man or animal; or (2) tests which are appropriate for the evaluation of the safety of additives in food suggest that the color additive, including its components or impurities, induces cancer in man or animal, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, cancer has been induced and whether the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable; and if the data considered as a whole establish that the color additive will be safe under the conditions that can be specified in the applicable regulation, it may be listed for such use. But if in the judgment of the Commissioner, based on information from qualified scientists, cancer has been induced, no regulation may issue which permits its use.

(b) *Color additives that will not be ingested.* Whenever the scientific data before the Commissioner suggest the possibility that the color additive, including its components or impurities, has induced cancer in man or animals by routes other than ingestion, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, the test suggesting the possibility of carcinogenesis is appropriate for the evaluation of the color additive for a use which does not involve ingestion, cancer has been induced, and the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable to preclude external drug and cosmetic uses, and if the data as a whole establish that the color additive will be safe under conditions that can be specified in the regulations, it may be listed for such use. But if, in the judgment of the Commissioner, based on information from qualified scientists, the test is an appropriate one for the consideration of safety for the proposed external use, and cancer has been induced by the color additive, including its components or impurities, no regulation may issue which permits its use in external drugs and cosmetics.

(c) *Color additives for use as an ingredient of feed for animals that are raised for food production.* Color additives that are an ingredient of the feed for animals raised for food production and that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of Subpart E of Part 500 of this chapter.

(Secs. 402, 403, 409, 512, 701(a), 706, 52 Stat. 1046-1048 as amended, 1055, 72 Stat. 1785-1788 as amended, 74 Stat. 399-403, 82 Stat. 343-351 (21 U.S.C. 342, 343, 348, 360b, 371(a), 376))

[42 FR 15636, Mar. 22, 1977, as amended at 43 FR 22675, May 26, 1978; 52 FR 49586, Dec. 31, 1987]

§ 70.51 Advisory committee on the applicability of the anticancer clause.

All requests for and procedures governing any advisory committee on the anticancer clause shall be subject to the provisions of Part 14 of this chapter, and particularly Subpart H of that part.

§ 70.55 Request for scientific studies.

The Commissioner will consider requests by any interested person who desires the Food and Drug Administration to conduct scientific studies to support a petition for a regulation for a color additive. If favorably acted upon, such studies will be limited to pharmacological investigations, studies of the chemical and physical structure of the color additive, and methods of analysis of the pure color additive (including impurities) and its identification and determination in foods, drugs, or cosmetics, as the case may be. All requests for such studies shall be accompanied by the fee prescribed in § 70.19.

PART 71—COLOR ADDITIVE PETITIONS

Subpart A—General Provisions

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71.2 Notice of filing of petition.
71.4 Samples; additional information.
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Subpart B—Administrative Action on Petitions

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71.22 Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued.
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71.27 Listing and exemption from certification on the Commissioner's initiative.
71.30 Procedure for filing objections to regulations.
71.37 Exemption of color additives for investigational use.

AUTHORITY: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376).

SOURCE: 42 FR 15639, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 71.1 Petitions.

(a) Any interested person may propose the listing of a color additive for use in or on any food, drug, or cosmetic or for coloring the human body. Such proposal shall be made in a petition in the form prescribed in paragraph (c) of this section. The petition shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petitioner shall state the post-office address in the United States to which published notices or orders issued or objections filed pursuant to section 706 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted the information. Any reference to published information offered in support of a color additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

————————(Date)

Name of petitioner ————————
Post-office address ————————
Name of color additive and proposed use —

————————————————

Division of Food and Color Additives,
HFF-330, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

Dear Sir:

Petitioner submits this pursuant to section 706(b)(1) of the Federal Food, Drug, and Cosmetic Act requesting listing by the Commissioner of the color additive ————as suitable and safe for use in or on ————subject to the conditions that ————. [Petitioner may propose a listing for general use in food, drugs, or cosmetics or, if such general listing is not believed suitable and safe, the petitioner shall describe the conditions under which he believes the additive can be safely used and for which it will be suitable. These conditions may include tolerance limitations, specifications as to the manner in which the additive may be added or used, and directions and other labeling or packaging safeguards that should be applied. The level of use proposed should not be higher than reasonably required to accomplish the intended color effect.]

Attached hereto in triplicate and constituting a part of this petition are the following:

A. The name and all pertinent information concerning the color additive, including chemical identity and composition of the color additive, its physical, chemical, and biological properties, and specifications prescribing its component(s) and identifying and limiting the reaction byproducts and other impurities.

The petition shall contain a description of the chemical and physical tests relied upon to identify the color additive and shall contain a full description of the methods used in, and the facilities and controls used for, the production of the color additive. These shall establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls, within reasonable limits, that do not affect the characteristics of the substance or the reliability of the controls may be specified.

The petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation of any straight color, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common or usual name and its complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitive statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a color additive, the petitioner shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to insure the identity, strength, quality, or purity of the color additive, the expiration period that will be employed as well as any packaging and labeling precautions needed to preserve stability.

B. The amount of the color additive proposed for use and the color effect intended to be achieved, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the color additive. If the color effect results or may reasonably be expected to result from use of the color additive in packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

Typewritten or other draft-labeling copy will be accepted for consideration of the petition provided final printed labeling identical in content to the draft copy is submitted as soon as available, and prior to the marketing of the color additive. The printed labeling shall conform in prominence and conspicuousness with the requirements of the act.

If the color additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance. If the safety data will not support the use of the amount of the color additive reasonably needed to accomplish the desired color effect, the requested tolerance will not be established. Petitioners are expected to propose the use of color additives in accordance with sound color chemistry.

C.1. A description of practicable methods to determine the pure color and all intermediates, subsidiary colors, and other components of the color additive.

2. A description of practicable methods to determine the amount of the color additive in any raw, processed, and/or finished food, drug, or cosmetic in which use of the color additive is proposed. (The tests proposed shall be those that can be used for food, drug, or cosmetic control purposes and can be applied with consistent results by any properly equipped laboratory and trained personnel.)

3. A description of methods for identification and determination of any substance formed in or on such food, drug, or cosmetic because of the use of the color additive. (If it is the petitioner's view that any such method would not be needed, under the terms of section 706(b)(5)(A)(iv), a statement shall be submitted in lieu of methods as to the basis for such view.)

D. Full reports of investigation made with respect to the safety of the color additive.

(A petition will be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the color additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any data that would influence the evaluation of the safety of the color additive).

E. Complete data which will allow the Commissioner to consider, among other things, the probable consumption of, and/or other relevant exposure from the additive and of any substance formed in or on food, drugs, or cosmetics because of such additive; and the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in the diet including, but not limited to food additives and pesticide chemicals for which tolerances or exemptions from tolerances have been established.

F. Proposed tolerances and other limitations on the use of the color additive, if tolerances and limitations are required in order to insure its safety. A petitioner may include a proposed regulation.

G. If exemption from batch certification is requested, the reasons why it is believed such certification is not necessary (including supporting data to establish the safety of the intended use).

H. If submitting a petition to alter an existing regulation issued pursuant to section 706(b) of the act, full information on each proposed change that is to be made in the original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

I. The prescribed fee of $ —— for admitting the color additive to listing is enclosed (unless there is an advance deposit adequate to cover the fee).

Yours very truly,
(Petitioner) ______________________
By____________(Indicate authority)

J. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

(d) The petitioner will be notified of the date on which his petition is filed; and an incomplete petition, or one that has not been submitted in triplicate, will be retained but not filed. A petition shall be retained but shall not be filed if any of the data listed in the above form are lacking or are not set forth so as to be readily understood or if the prescribed fee has not been submitted. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or authorized agent, who is a resident of the United States.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier petition.

(g) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 706(b) of the act shall include with respect to each nonclinical study contained in the petition, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(h) [Reserved]

(i) If clinical investigations involving human subjects are involved, petitions filed with the Commissioner under section 706(b) of the act shall include statements regarding each such clinical investigation contained in the petition that it either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter, or was not subject to such requirements in accordance with §§ 56.104 or 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in Part 50 of this chapter.

(Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055-1056, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 351, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360i, 371, 376); secs. 215, 301, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended; 42 U.S.C. 216, 241, 262, 263b-263n)

[42 FR 15639, Mar. 22, 1977, as amended at 43 FR 60021, Dec. 22, 1978; 46 FR 8952, Jan. 27, 1981; 50 FR 7491, Feb. 22, 1985; 50 FR 16668, Apr. 26, 1985]

§ 71.2 Notice of filing of petition.

(a) Except where the petition involves a new drug, the Commissioner, within 15 days after receipt, will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 706(d)(1) of the act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing. Where the petition involves a new drug or certifiable antibiotic, notification to the petitioner will be made in accordance with § 70.10(b)(3) of this chapter.

(b) The Commissioner will cause to be published in the Federal Register within 30 days from the date of filing of such petition a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. A copy of the notice will be mailed to the petitioner when the original document is signed.

§ 71.4 Samples; additional information.

The Commissioner may request samples of the color additive, articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, and any additional information needed to clarify a submitted method or other aspect of a petition at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the color additive, or articles used as components thereof, or of the food, drug, or cosmetic in which the color additive is proposed to be used, or which comprises the color additive, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the color additive present in products for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the color additive or the physical or technical effect it produces. The date used for computing the 90-day limit for the purposes of section 706(d)(1) of the act shall be moved forward 1 day for each day, after mailing date of the request, taken by the petitioner to submit the information and/or sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

(a) *Extension of time for studying petitions.* If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

(b) *Substantive amendments.* After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amounts to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical laboratory study contained in the petition, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. If clinical investigations involving human subjects are involved, additional information or data submitted in support of filed petitions shall include statements regarding each such clinical investigation from which the information or data are derived, that it either was conducted in compliance with the requirements for institutional review set forth in Part 56 of this chapter, or was not subject to such requirements in accordance with §§ 56.104 or 56.105, and that it was conducted in compliance with the requirements for informed consent set forth in Part 50 of this chapter.

(c) *Withdrawal of petitions without prejudice.* (1) In some cases the Commissioner may notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a regulation or the regulation requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal will be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling.

(2) At any time before the order provided for in § 71.20 has been forwarded to the FEDERAL REGISTER for publication the petitioner may withdraw the petition without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew.

(Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055-1056 as amended, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 74 Stat. 399-407 as amended 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 351, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360i, 371, 376); secs. 215, 301, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended; 42 U.S.C. 216, 241, 262, 263b-263n)

[42 FR 15636, Mar. 22, 1977, as amended at 43 FR 60021, Dec. 22, 1978; 46 FR 8952, Jan. 27, 1981; 50 FR 7491, Feb. 22, 1985]

§ 71.15 Confidentiality of data and information in color additive petitions.

(a) The following data and information in a color additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the FEDERAL REGISTER or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

(1) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(4) A list of all ingredients contained in a color additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 20.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(6) All records showing the Food and Drug Administration's testing of or action on a particular lot of a certifiable color additive.

(b) The following data and information in a color additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(c) All correspondence and written summaries of oral discussions relating to a color additive petition are available for public disclosure in accordance with the provisions of Part 20 of this chapter when the color additive regulation is published in the FEDERAL REGISTER.

(d) For purposes of this regulation, safety and functionality data include all studies and tests of a color additive on animals and humans and all studies and tests on a color additive for identity, stability, purity, potency, performance, and usefulness.

§ 71.18 Petition for exemption from certification.

A manufacturer, packer, or distributor of a color additive or color additive mixture may petition for an exemption from certification pursuant to Part 10 of this chapter. Any such petition shall show why such certification is not necessary for the protection of public health.

Subpart B—Administrative Action on Petitions

§ 71.20 Publication of regulation.

The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 706(d)(1) of the act):

(a) A regulation listing in Part 73 or 74 of this chapter the color additive on the appropriate list or lists as provided under section 706(b)(1).

(1) Such a regulation may list the color additive for use generally in or on foods, drugs, or cosmetics or for use in coloring the human body, as the case may be, or may prescribe the conditions under which the color additive may be safely used (including, but not limited to, specifications as to the particular food, drug, or cosmetic or classes of food, drugs, or cosmetics in or on which such color additive may be used, or for the material intended for coloring the human body; the maximum quantity of any straight color or diluent that may be used or permitted to remain in or on such food, drug, or cosmetic or article intended for coloring the human body; the manner in which such color additive may be added to or used in or on such food, drug, or cosmetic or for coloring the human body; and any directions or other labeling or packing requirements for such color additives deemed necessary to assure the safety of such use).

(2) Such regulations shall list the color additive only for the use or uses for which it has been found suitable and for which it may safely be employed. Alternatively, the Commissioner shall by order deny the petition, and notify the petitioner of such order and the reasons therefor.

(b) Whenever the Commissioner finds that batch certification is not necessary for the protection of the public health he will, by order, exempt the color additive from the certification procedure. In determining whether certification of a color additive is necessary, the Commissioner will consider the composition of the additive, its manufacturing process, possible impurities, its toxic potential, control and analytical procedures necessary to assure compliance with the listing specifications, and the variability of its composition.

§ 71.22 Deception as a basis for refusing to issue regulations; deceptive use of a color additive for which a regulation has issued.

The Commissioner shall refuse to issue a regulation listing a color additive, if in his judgment the data before him show that such proposed use would promote deception of the consumer or would result in misbranding or adulteration within the meaning of the act. Such a finding shall be by order published in the FEDERAL REGISTER subject to the filing of objections and a request for a hearing by adversely affected parties. The issuance of a regulation for a color additive authorizing its use generally in or on a food, drug, or cosmetic shall not be construed as authorization to use the color additive in a manner that may promote deception or conceal damage or inferiority. The use of a color additive to promote deception or conceal damage or inferiority shall be considered as the use of a color additive for which no regulation has issued pursuant to section 706(b) of the act, even though the regulation is effective for other uses.

§ 71.25 Condition for certification.

(a) When the Commissioner cannot conclude from the information before him that there is a basis for exempting a color additive from the requirement of batch certification, he will so order by appropriate listing in Part 74 of this chapter. The Commissioner's order shall state in detail the specifications that shall be met by the color additive.

(b) Each order shall state a period of time after which use of a color additive subject to batch certification but not from a batch certified by procedure prescribed in this section would result in adulteration of the product in which it is used.

§ 71.26 Revocation of exemption from certification.

If information becomes available to the Commissioner that a color additive that has been granted exemption from certification should not, for the protection of the public health, be so exempted, such exemption will be canceled by a notice published in the FEDERAL REGISTER.

§ 71.27 Listing and exemption from certification on the Commissioner's initiative.

Where a petition for a regulation to list a color additive has not been received and the Commissioner has available facts which demonstrate that a color additive should be listed and/or that certification procedure is not necessary in order to protect the public health, he may list such color additive by appropriate regulation and listing in Part 73 or 74 of this chapter.

§ 71.30 Procedure for filing objections to regulations.

(a) Objections and hearings relating to color additive regulations under section 706 (b) and (c) of the act shall be governed by Parts 10, 12, 13, 14, 15, 16, and 19 of this chapter.

(b) The fees specified in § 70.19 of this chapter shall be applicable.

§ 71.37 Exemption of color additives for investigational use.

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which states prominently, "Caution—Contains new color additive—For investigational use only." No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Subpart A—Foods

Sec.
73.1 Diluents in color additive mixtures for food use exempt from certification.
73.30 Annatto extract.
73.40 Dehydrated beets (beet powder).
73.50 Ultramarine blue.
73.75 Canthaxanthin.
73.85 Caramel.
73.90 β-Apo-8'-carotenal.
73.95 β-Carotene.
73.100 Cochineal extract; carmine.
73.140 Toasted partially defatted cooked cottonseed flour.
73.160 Ferrous gluconate.
73.169 Grape color extract.
73.170 Grape skin extract (enocianina).
73.200 Synthetic iron oxide.
73.250 Fruit juice.
73.260 Vegetable juice.
73.275 Dried algae meal.
73.295 Tagetes (Aztec marigold) meal and extract.
73.300 Carrot oil.
73.315 Corn endosperm oil.
73.340 Paprika.
73.345 Paprika oleoresin.
73.450 Riboflavin.
73.500 Saffron.
73.575 Titanium dioxide.
73.600 Turmeric.

Sec.
73.615 Turmeric oleoresin.

Subpart B—Drugs

73.1001 Diluents in color additive mixtures for drug use exempt from certification.
73.1010 Alumina (dried aluminum hydroxide).
73.1015 Chromium-cobalt-aluminum oxide.
73.1025 Ferric ammonium citrate.
73.1030 Annatto extract.
73.1070 Calcium carbonate.
73.1075 Canthaxanthin.
73.1085 Caramel.
73.1095 β-Carotene.
73.1100 Cochineal extract; carmine.
73.1125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
73.1150 Dihydroxyacetone.
73.1162 Bismuth oxychloride.
73.1200 Synthetic iron oxide.
73.1298 Ferric ammonium ferrocyanide.
73.1299 Ferric ferrocyanide.
73.1326 Chromium hydroxide green.
73.1327 Chromium oxide greens.
73.1329 Guanine.
73.1375 Pyrogallol.
73.1400 Pyrophyllite.
73.1410 Logwood extract.
73.1496 Mica.
73.1550 Talc.
73.1575 Titanium dioxide.
73.1645 Aluminum powder.
73.1646 Bronze powder.
73.1647 Copper powder.
73.1991 Zinc oxide

Subpart C—Cosmetics

73.2030 Annatto.
73.2085 Caramel.
73.2087 Carmine.
73.2095 B-Carotene.
73.2110 Bismuth citrate.
73.2120 Disodium EDTA-copper.
73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).
73.2150 Dihydroxyacetone.
73.2162 Bismuth oxychloride.
73.2180 Guaiazulene.
73.2190 Henna.
73.2250 Iron oxides.
73.2298 Ferric ammonium ferrocyanide.
73.2299 Ferric ferrocyanide.
73.2326 Chromium hydroxide green.
73.2327 Chromium oxide greens.
73.2329 Guanine.
73.2396 Lead acetate.
73.2400 Pyrophyllite.
73.2496 Mica.
73.2500 Silver.
73.2575 Titanium dioxide.
73.2645 Aluminum powder.
73.2646 Bronze powder.
73.2647 Copper powder.
Sec.
73.2725 Ultramarines.
73.2775 Manganese violet.
73.2991 Zinc oxide.

Subpart D—Medical Devices

73.3105 1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione.
73.3107 Carbazole violet.
73.3110 Chlorophyllin-copper complex, oil soluble.
73.3110a Chromium-cobalt-aluminum oxide.
73.3111 Chromium oxide greens.
73.3112 C.I. Vat Orange 1.
73.3115 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thiol]phenyl]azo]-1,3,5-benzenetriol.
73.3117 16,23-Dihydrodinaphtho[2,3-a:2',3'-i] naphth [2',3':6,7] indolo [2,3-c] carbazole-5,10,15,17,22,24-hexone.
73.3118 N,N'-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide.
73.3119 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.
73.3120 16,17-Dimethoxydinaphtho [1,2,3-cd:3',2',1'-lm] perylene-5,10-dione.
73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.
73.3122 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one.
73.3123 6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene) benzo[b]thiophen-3 (2H)-one.
73.3124 Phthalocyanine green.
73.3125 Iron oxides.
73.3126 Titanium dioxide.

AUTHORITY: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

SOURCE: 42 FR 15643, Mar. 22, 1977, unless otherwise noted.

Subpart A—Foods

§ 73.1 Diluents in color additive mixtures for food use exempt from certification.

The following substances may be safely used as diluents in color additive mixtures for food use exempt from certification, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. If a specification for a particular diluent is not set forth in this Part 73, the material shall be of a purity consistent with its intended use.

(a) *General use.* (1) Substances that are generally recognized as safe under the conditions set forth in section 201(s) of the act.

(2) Substances meeting the definitions and specifications set forth under Subchapter B of this chapter, and which are used only as prescribed by such regulations.

(3) The following:

Substances	Definitions and specifications	Restrictions
Castor oil	As set forth in U.S.P. XVI	Not more than 500 p.p.m. in the finished food. Labeling of color additive mixtures containing castor oil shall bear adequate directions for use that will result in a food meeting this restriction.
Dioctylsodium sulfosuccinate	As set forth in sec. 172.810 of this chapter.	Not more than 9 p.p.m. in the finished food. Labeling of color additive mixtures containing dioctylsodium sulfosuccinate shall bear adequate directions for use that will result in a food meeting this restriction.

(b) *Special use*—(1) *Diluents in color additive mixtures for marking food*—(i) *Inks for marking food supplements in tablet form, gum, and confectionery.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, SDA-3A	As set forth in 26 CFR pt. 212	No residue.
n-Butyl alcohol		Do.
Cetyl alcohol	As set forth in N.F. XI	Do.
Cyclohexane		Do.
Ethyl cellulose	As set forth in sec. 172.868 of this chapter.	
Ethylene glycol monoethyl ether		Do.
Isobutyl alcohol		Do.
Isopropyl alcohol		Do.
Polyoxyethylene sorbitan monooleate (polysorbate 80)	As set forth in sec. 172.840 of this chapter.	
Polyvinyl acetate	Molecular weight, minimum 2,000	
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	
Rosin and rosin derivatives	As set forth in sec. 172.615 of this chapter.	
Shellac, purified	Food grade	

(ii) *Inks for marking fruit and vegetables.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Acetone	As set forth in N.F. XI	No residue.
Alcohol, SDA-3A	As set forth in 26 CFR pt. 212	Do.
Benzoin	As set forth in U.S.P. XVI	
Copal, Manila		
Ethyl acetate	As set forth in N.F. XI	Do.
Ethyl cellulose	As set forth in sec. 172.868 of this chapter.	
Methylene chloride		Do.
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	
Rosin and rosin derivatives	As set forth in sec. 172.615 of this chapter.	
Silicon dioxide	As set forth in sec. 172.480 of this chapter.	Not more than 2 pct of the ink solids.
Terpene resins, natural	As set forth in sec. 172.615 of this chapter.	

Substances	Definitions and specifications	Restrictions
Terpene resins, synthetic	Polymers of α- and β-pinene	

(2) *Diluents in color additive mixtures for coloring shell eggs.* Items listed in paragraph (a) of this section and the following, subject to the condition that there is no penetration of the color additive mixture or any of its components through the eggshell into the egg:

Alcohol, denatured, formula 23A (26 CFR Part 212), Internal Revenue Service.
Damar gum (resin).
Diethylene glycol distearate.
Dioctyl sodium sulfosuccinate.
Ethyl cellulose (as identified in § 172.868 of this chapter).
Ethylene glycol distearate.
Japan wax.
Limed rosin.
Naphtha.
Pentaerythritol ester of fumaric acid-rosin adduct.
Polyethylene glycol 6000 (as identified in § 172.820 of this chapter).
Polyvinyl alcohol.
Rosin and rosin derivatives (as identified in § 172.820 of this chapter).

(3) *Miscellaneous special uses.* Items listed in paragraph (a) of this section and the following:

Substances	Definitions and specifications	Restrictions
Polyvinylpyrrolidone	As set forth in sec. 173.55 of this chapter.	In or as food-tablet coatings; limit, not more than 0.1 pct in the finished food; labeling of color additive mixtures containing polyvinylpyrrolidone shall bear adequate directions for use that will result in a food meeting this restriction.

§ 73.30 Annatto extract.

(a) *Identity.* (1) The color additive annatto extract is an extract prepared from annatto seed, *Bixa orellana* L., using any one or an appropriate combination of the food-grade extractants listed in paragraph (a)(1) (i) and (ii) of this section:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this section. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichlorethylene.

(2) Color additive mixtures for food use made with annatto extract may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead as Pb, not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this section are used, annatto extract shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in Parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section

401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this section.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.40 Dehydrated beets (beet powder).

(a) *Identity.* (1) The color additive dehydrated beets is a dark red powder prepared by dehydrating sound, mature, good quality, edible beets.

(2) Color additive mixtures made with dehydrated beets may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive shall conform to the following specifications:

Volatile matter, not more than 4 percent.
Acid insoluble ash, not more than 0.5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Dehydrated beets may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.50 Ultramarine blue.

(a) *Identity.* The color additive ultramarine blue is a blue pigment obtained by calcining a mixture of kaolin, sulfur, sodium carbonate, and carbon at temperatures above 700° C. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfo-silicate having the approximate formula $Na_7Al_6Si_6O_{24}S_3$.

(b) *Specifications.* Ultramarine blue shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The color additive ultramarine blue may be safely used for coloring salt intended for animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5 percent by weight of the salt.

(d) *Labeling requirements.* The color additive shall be labeled in accordance with the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.75 Canthaxanthin.

(a) *Identity.* (1) The color additive canthaxanthin is β-carotene-4,4′-dione.

(2) Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are

suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Canthaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Physical state, solid.
1 percent solution in chloroform, complete and clear.
Melting range (decomposition), 207° C. to 212° C. (corrected).
Loss on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Total carotenoids other than trans-canthaxanthin, not more than 5 percent.
Lead, not more than 10 parts per million.
Arsenic, not more than 3 parts per million.
Mercury, not more than 1 part per million.
Assay, 96 to 101 percent.

(c) *Use and restrictions.* (1) The color additive canthaxanthin may be safely used for coloring foods generally subject to the following restrictions:

(i) The quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food.

(ii) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(2) Canthaxanthin may be safely used in broiler chicken feed to enhance the yellow color of broiler chicken skin in accordance with the following conditions: The quantity of canthaxanthin incorporated in the feed shall not exceed 4.41 milligrams per kilogam (4 grams per ton) of complete feed to supplement other known sources of xanthophyll and associated carotenoids to accomplish the intended effect.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 50 FR 47534, Nov. 19, 1985]

§ 73.85 Caramel.

(a) *Identity.* (1) The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates:

Dextrose.
Invert sugar.
Lactose.
Malt sirup.
Molasses.
Starch hydrolysates and fractions thereof.
Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.

(i) Acids:

Acetic acid.
Citric acid.
Phosphoric acid.
Sulfuric acid.
Sulfurous acid.

(ii) Alkalis:

Ammonium hydroxide.
Calcium hydroxide U.S.P.
Potassium hydroxide.
Sodium hydroxide.

(iii) Salts: Ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(3) Polyglycerol esters of fatty acids, identified in § 172.854 of this chapter, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Caramel shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 0.1 part per million.

(c) *Uses and restrictions.* Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.90 β-Apo-8′-carotenal.

(a) *Identity.* (1) The color additive is β-apo-8′-carotenal.

(2) Color additive mixtures for food use made with β-apo-8′-carotenal may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* β-Apo-8′-carotenal shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Melting point (decomposition), 136° C.-140° C. (corrected).
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Assay (spectrophotometric), 96-101 percent.

(c) *Uses and restrictions.* The color additive β-apo-8′-carotenal may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β-apo-8′-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.95 β-Carotene.

(a) *Identity.* (1) The color additive is β-carotene prepared synthetically or obtained from natural sources.

(2) Color additive mixtures for food use made with β-carotene may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* β-carotene shall conform to the following specifications:

Physical state, solid.
1 percent solution in chloroform, clear.
Loss of weight on drying, not more than 0.2 percent.
Residue on ignition, not more than 0.2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Assay (spectrophotometric), 96-101 percent.

(c) *Uses and restrictions.* The color additive β-carotene may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color those foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.100 Cochineal extract; carmine.

(a) *Identity.* (1) The color additive cochineal extract is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic extract of cochineal (*Dactylopius coccus costa* (*Coccus cacti*L.)). The coloring principle is chiefly carminic acid.

(2) The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal (*Dactylopius coccus costa* (*Coccus cacti*L.)).

(3) Color additive mixtures for food use made with cochineal extract or carmine may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* (1) Cochineal extract shall conform to the following specifications:

pH, not less than 5.0 and not more than 5.5 at 25° C.
Protein (N × 6.25), not more than 2.2 percent.
Total solids, not less than 5.7 and not more than 6.3 percent.
Methyl alcohol, not more than 150 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 1.8 percent.

(2) Carmine shall conform to the following specifications:

Volatile matter (at 135° C. for 3 hours), not more than 20.0 percent.
Ash, not more than 12.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 50.0 percent.

Carmine and cochineal extract shall be pasteurized or otherwise treated to destroy all viable Salmonella microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine and cochineal extract free of viable Salmonella microorganisms, which substances are not food additives as defined in section 201(s) of the act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the act.

(c) *Uses and restrictions.* Carmine and cochineal extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.140 Toasted partially defatted cooked cottonseed flour.

(a) *Identity.* (1) The color additive toasted partially defatted cooked cottonseed flour is a product prepared as follows: Food quality cottonseed is delinted and decorticated; the meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown.

(2) Color additive mixtures for food use made with toasted partially defatted cooked cottonseed flour may contain only diluents that are suitable

and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) *Specifications.* Toasted partially defatted cooked cottonseed flour shall conform to the following specifications:

Arsenic: It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

Lead (as Pb), not more than 10 parts per million.

Free gossypol content, not more than 450 parts per million.

(c) *Uses and restrictions.* The color additive toasted partially defatted cooked cottonseed flour may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.160 Ferrous gluconate.

(a) *Identity.* The color additive ferrous gluconate is the ferrous gluconate defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 122-123, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(b) *Specifications.* Ferrous gluconate shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a) of this section.

(c) *Uses and restrictions.* Ferrous gluconate may be safely used in amounts consistent with good manufacturing practice for the coloring of ripe olives.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 15643, Mar. 22, 1977, as amended at 47 FR 946, Jan. 8, 1982; 49 FR 10089, Mar. 19, 1984]

§ 73.169 Grape color extract.

(a) *Identity.* (1) The color additive grape color extract is an aqueous solution of anthocyanin grape pigments made from Concord grapes or a dehydrated water soluble powder prepared from the aqueous solution. The aqueous solution is prepared by extracting the pigments from precipitated lees produced during the storage of Concord grape juice. It contains the common components of grape juice, namely anthocyanins, tartrates, malates, sugars, and minerals, etc., but not in the same proportion as found in grape juice. The dehydrated water soluble powder is prepared by spray drying the aqueous solution containing added malto-dextrin.

(2) Color additive mixtures for food use made with grape color extract may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Grape color extract shall conform to the following specifications: Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act. Lead (as Pb), not more than 10 parts per million. Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions.* Grape color extract may be safely used for the coloring of nonbeverage food, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches are exempt from the certification requirements of section 706(c) of the Act.

[46 FR 47532, Sept. 29, 1981]

§ 73.170 Grape skin extract (enocianina).

(a) *Identity.* (1) The color additive grape skin extract (enocianina) is a purplish-red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes have been pressed to produce grape juice or wine. It contains the common components of grape juice; namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the steeping process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol. The extract is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulphur dioxide may be present.

(2) Color additive mixtures for food use made with grape skin extract (enocianina) may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Grape skin extract (enocianina) shall conform to the following specifications:

Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

(c) *Uses and restrictions.* Grape skin extract (enocianina) may be safely used for the coloring of still and carbonated drinks and ades, beverage bases, and alcoholic beverages subject to the following restrictions:

(1) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless artificial color is authorized by such standards.

(2) Its use in alcoholic beverages shall be in accordance with the provisions of Parts 4 and 5, title 27 CFR.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. The common or usual name of the color additive is "grape skin extract" followed, if desired, by "(enocianina)".

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for dog and cat food use made with synthetic iron oxide may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Synthetic iron oxide shall conform to the following specifications, all on an "as is" basis:

Arsenic (as As), not more than 5 parts per million.

Lead (as Pb), not more than 20 parts per million.

Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25 percent by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.250 Fruit juice.

(a) *Identity.* (1) The color additive fruit juice is the concentrated or unconcentrated liquid expressed from mature varieties of fresh, edible fruits, or is a water infusion of the dried fruit. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.260 Vegetable juice.

(a) *Identity.* (1) The color additive vegetable juice is the concentrated or unconcentrated liquid expressed from mature varieties of fresh, edible vegetables. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under section 401 of the act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.275 Dried algae meal.

(a) *Identity.* The color additive dried algae meal is a dried mixture of algae cells (genus *Spongiococcum*, separated from its culture broth), molasses, cornsteep liquor, and a maximum of 0.3 percent ethoxyquin. The algae cells

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are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

(b) *Uses and restrictions.* The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (b)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(c) *Labeling.* The label of the color additives and any premixes prepared therefrom shall bear in addition to the information required by § 70.25 of this chapter.

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this section.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.295 Tagetes (Aztec marigold) meal and extract.

(a) *Identity.* (1) The color additive tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (*Tagetes erecta* L.) mixed with not more than 0.3 percent ethoxyquin.

(2) The color additive tagetes (Aztec marigold) extract is a hexane extract of the flower petals of the Aztec marigold (*Tagetes erecta* L.). It is mixed with an edible vegetable oil, or with an edible vegetable oil and a hydrogenated edible vegetable oil, and not more than 0.3 percent ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

(b) *Specifications.* (1) Tagetes (Aztec marigold) meal is free from admixture with other plant materiel from *Tageteserecta* L. or from plant material or flowers of any other species of plants.

(2) Tagetes (Aztec marigold) extract shall be prepared from tagetes (Aztec marigold) petals meeting the specifications set forth in paragraph (b)(1) of this section and shall conform to the following additional specifications:

Melting point	53.5°–55.0° C.
Iodine value	132–145.
Saponification value	175–200.
Acid value	0.60–1.20.
Titer	35.5°–37.0° C.
Unsaponifiable matter	23.0 percent–27.0 percent.
Hexane residue	Not more than 25 p.p.m.

All determinations, except the hexane residue, shall be made on the initial extract of the flower petals (after drying in a vacuum oven at 60° C. for 24 hours) prior to the addition of the oils and ethoxyquin. The hexane determination shall be made on the color additive after the addition of the vegetable oils, hydrogenated vegetable oils, and ethoxyquin.

(c) *Uses and restrictions.* The color additives tagetes (Aztec marigold) meal and extract may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additives are used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additives incorporated in the feed is such that the finished feed:

(i) Is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section; and

(ii) Meets the tolerance limitation for ethoxyquin in animal feed prescribed in § 573.380 of this chapter.

(d) *Labeling requirements.* The label of the color additives and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter:

(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.

(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this section.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.300 Carrot oil.

(a) *Identity.* (1) The color additive carrot oil is the liquid or the solid portion of the mixture or the mixture itself obtained by the hexane extraction of edible carrots (*Daucus carota* L.) with subsequent removal of the hexane by vacuum distillation. The resultant mixture of solid and liquid extractives consists chiefly of oils, fats, waxes, and carrotenoids naturally occurring in carrots. The definition of carrot oil in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for carrot oil or carrot oleoresin under section 401 of the act.

(2) Color additive mixtures for food use made with carrot oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Carrot oil shall contain no more than 25 parts per million of hexane.

(c) *Uses and restrictions.* Carrot oil may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless the use of added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.315 Corn endosperm oil.

(a) *Identity.* (1) The color additive corn endosperm oil is a reddish-brown liquid composed chiefly of glycerides, fatty acids, sitosterols, and carotenoid pigments obtained by isopropyl alcohol and hexane extraction from the gluten fraction of yellow corn grain. The definition of corn endosperm oil in this paragraph is for the purpose of definition as a color additive only and shall not be construed as a food standard of identity under section 401 of the act.

(2) Color additive mixtures for food use made with corn endosperm oil may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Corn endosperm oil conforms to the following specifications:

Total fatty acids, not less than 85 percent.
Iodine value, 118 to 134.
Saponification value, 165 to 185.
Unsaponifiable matter, not more than 14 percent.
Hexane, not more than 25 parts per million.
Isopropyl alcohol, not more than 100 parts per million.

(c) *Uses and restrictions.* The color additive corn endosperm oil may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this section.

(d) *Labeling requirements.* The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required by § 70.25 of this chapter, a statement of the concentration of xanthophyll contained therein.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.340 Paprika.

(a) *Identity.* (1) The color additive paprika is the ground dried pod of mild capsicum (*Capsicum annuum* L.). The definition of paprika in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for paprika under section 401 of the act.

(2) Color additive mixtures made with paprika may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Paprika may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.345 Paprika oleoresin.

(a) *Identity.* (1) The color additive paprika oleoresin is the combination of flavor and color principles obtained from paprika (*Capsicum annuum* L.) by extraction, using any one or a combination of the following solvents:

Acetone.
Ethyl alcohol.
Ethylene dichloride.
Hexane.
Isopropyl alcohol.
Methyl alcohol.
Methylene chloride.
Trichloroethylene.

The definition of paprika oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for paprika oleoresin under section 401 of the act.

(2) Color additive mixtures made with paprika oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Paprika oleoresin shall contain no more residue of the solvents listed in paragraph (a)(1) of this section than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in Parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Paprika oleoresin may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.450 Riboflavin.

(a) *Identity.* (1) The color additive riboflavin is the riboflavin defined in the Food Chemicals Codex, 3d Ed. (1981), pp. 262-263, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Color additive mixtures made with riboflavin may contain as diluents only those substances listed in this subpart as safe and suitable for use in color additive mixtures for coloring foods.

(b) *Specifications.* Riboflavin shall meet the specifications given in the Food Chemicals Codex, 3d Ed. (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this section.

(c) *Uses and restrictions.* Riboflavin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice; except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the Act.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 15643, Mar. 22, 1977, as amended at 47 FR 947, Jan. 8, 1982; 49 FR 10089, Mar. 19, 1984]

§ 73.500 Saffron.

(a) *Identity.* (1) The color additive saffron is the dried stigma of Crocus sativus L. The definition of saffron in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for saffron under section 401 of the act.

(2) Color additive mixtures made with saffron may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Saffron may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.575 Titanium dioxide.

(a) *Identity.* (1) The color additive titanium dioxide is synthetically prepared TiO_2, free from admixture with other substances.

(2) Color additive mixtures for food use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods, and the following: Silicon dioxide, SiO_2 and/or aluminum oxide, Al_2O_3, as dispersing aids—not more than 2 percent total.

(b) *Specifications.* Titanium dioxide shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Antimony (as Sb), not more than 2 parts per million.

Mercury (as Hg), not more than 1 part per million.

Loss on ignition at 800° C. (after drying for 3 hours at 105° C.), not more than 0.5 percent.

Water soluble substances, not more than 0.3 percent.

Acid soluble substances, not more than 0.5 percent.

TiO_2, not less than 99.0 percent after drying for 3 hours at 105° C.

Lead, arsenic, and antimony shall be determined in the solution obtained by boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1 percent by weight of the food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.600 Turmeric.

(a) *Identity.* (1) The color additive turmeric is the ground rhizome of Curcuma longa L. The definition of turmeric in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric under section 401 of the act.

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Uses and restrictions.* Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(c) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.615 Turmeric oleoresin.

(a) *Identity.* (1) The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (Curcuma longa L.) by extraction using any one or a combination of the following solvents:

Acetone.
Ethyl alcohol.
Ethylene dichloride.
Hexane.
Isopropyl alcohol.
Methyl alcohol.
Methylene chloride.
Trichloroethylene.

The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under section 401 of the act.

(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this section than is permitted for the corresponding solvents in spice oleoresins under applicable food additive regulation in Parts 170 through 189 of this chapter.

(c) *Uses and restrictions.* Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act, unless the use of added color is authorized by such standards.

(d) *Labeling.* The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the act, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

Subpart B—Drugs

§ 73.1001 Diluents in color additive mixtures for drug use exempt from certification.

The following diluents may be safely used in color additive mixtures that are exempt from certification and which are to be used for coloring drugs, subject to the condition that each straight color in the mixture has been exempted from certification or, if not so exempted, is from a batch that has previously been certified and has not changed in composition since certification. Such listing of diluents is not to be construed as superseding any of the other requirements of the Federal Food, Drug, and Cosmetic Act with respect to drugs, including new drugs. If a definition and specification for a particular diluent is not set forth in this subpart, the material shall be of a purity consistent with its intended use.

(a) *Ingested drugs*—(1) *General use.* Diluents listed in § 73.1(a) and the following:

Substances	Definitions and specifications	Restrictions
Alcohol, specially denatured	As set forth in 26 CFR, pt. 212	As set forth in 26 CFR, pt. 211
Cetyl alcohol	As set forth in N.F. XI	
Isopropyl alcohol		In color coatings for pharmaceutical forms, no residue.
Polyoxyethylene (20) sorbitan monostearate (Polysorbate 60)	As set forth in sec. 172.836 of this chapter	
Polyoxyethylene (20) sorbitan tristearate (Polysorbate 65)	As set forth in sec. 172.838 of this chapter	
Polysorbate 80	As set forth in sec. 172.840 of this chapter	
Polyvinyl-pyrrolidone	As set forth in sec. 173.55 of this chapter	
Sorbitan monooleate		
Sorbitan monostearate	As set forth in sec. 172.842 of this chapter	
Sorbitan trioleate		

(2) *Special use; inks for branding pharmaceutical forms.* Items listed in paragraph (a)(1) of this section, § 73.1(b)(1)(i), and the following:

Ethyl lactate.
Polyoxyethylene sorbitan monolaurate (20).

(b) *Externally applied drugs.* Diluents listed in paragraph (a)(1) of this section and the following:

Substances	Definitions and specifications
Benzyl alcohol	As set forth in N.F. XI
Ethyl cellulose	As set forth in § 172.868 of this chapter
Hydroxyethyl cellulose	
Hydroxypropyl cellulose	As set forth in § 172.870 of this chapter

§ 73.1010 Alumina (dried aluminum hydroxide).

(a) *Identity.* (1) The color additive alumina (dried aluminum hydroxide) is a white, odorless, tasteless, amorphous powder consisting essentially of aluminum hydroxide ($Al_2O_3 \cdot XH_2O$).

(2) Color additive mixtures for drug use made with alumina (dried aluminum hydroxide) may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Alumina (dried aluminum hydroxide) shall conform to the following specifications:

Acidity or alkalinity: Agitate 1 gram of the color additive with 25 milliliters of water and filter. The filtrate shall be neutral to litmus paper.
Matter insoluble in dilute hydrochloric acid, not more than 0.5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

Aluminum oxide (Al_2O_3), not less than 50 percent.

(c) *Uses and restrictions.* Alumina (dried aluminum hydroxide) may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1015 Chromium-cobalt-aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide is a blue-green pigment obtained by calcining a mixture of chromium oxide, cobalt carbonate, and aluminum oxide. It may contain small amounts (less than 1 percent each) of oxides of barium, boron, silicon, and nickel.

(b) *Specifications.* Chromium-cobalt-aluminum oxide shall conform to the following specifications:

Chromium, calculated as Cr_2O_3, 34-37 percent.
Cobalt, calculated as CoO, 29-34 percent.
Aluminum, calculated as AL_2O_3, 29-35 percent.
Lead (as Pb), not more than 30 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total oxides of aluminum, chromium, and cobalt not less than 97 percent.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the chromium-cobalt-aluminum oxide for 15 minutes in 50 milliliters of 0.5 *N* hydrochloric acid.

(c) *Uses and restrictions.* The color additive chromium-cobalt-aluminum oxide may be safely used for coloring linear polyethylene surgical sutures, United States Pharmacopeia (U.S.P.), for use in general surgery, subject to the following restrictions:

(1) For coloring procedure, the color additive is blended with the polyethylene resin. The mixture is heated to a temperature of 500°-550° F. and extruded through a fixed orifice. The filaments are cooled, oriented by drawing, and set by annealing.

(2) The quantity of the color additive does not exceed 2 percent by weight of the suture material.

(3) The dyed suture shall conform in all respects to the requirements of the U.S.P. XX (1980).

(4) When the sutures are used for the purpose specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(5) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and batches thereof are exempt from the certification requirements of section 706(c) of the act.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1025 Ferric ammonium citrate.

(a) *Identity.* The color additive ferric ammonium citrate consists of complex chelates prepared by the interaction of ferric hydroxide with citric acid in the presence of ammonia. The complex chelates occur in brown and green forms, are deliquescent in air, and are reducible by light.

(b) *Specifications.* Ferric ammonium citrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Iron (as Fe), not less than 14.5 percent and not more than 18.5 percent.
Lead (as Pb), not more than 20 p/m.
Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Ferric ammonium citrate may be safely used in combination with pyrogallol (as listed in § 73.1375), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery subject to the following conditions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The labeling of the color-additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 706(c) of the act.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1030 Annatto extract.

(a) *Identity and specifications.* (1) The color additive annatto extract shall conform in identity and specifications to the requirements of § 73.30(a)(1) and (b).

(2) Color additive mixtures for drug use made with annatto extract may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* Annatto extract may be safely used for coloring drugs generally, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of § 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in § 73.30(a)(1)(ii) of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are evempt from the certification requirements of section 706(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 42 FR 36994, July 19, 1977]

§ 73.1070 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white, synthetically prepared powder consisting essentially of precipitated calcium carbonate ($CaCO_3$).

(2) Color additive mixtures for drug use made with calcium carbonate may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Calcium carbonate shall meet the specifications for precipitated calcium carbonate in the United States Pharmacopeia XX (1980).

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manudacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74

Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1075 Canthaxanthin.

(a) *Identity and specifications.* (1) The color additive canthaxanthin shall conform in identity and specifications to the requirements of § 73.75(a)(1) and (b).

(2) Color additive mixtures for ingested drug use made with canthaxanthin may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* Canthaxanthin may be safely used for coloring ingested drugs generally in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1085 Caramel.

(a) *Identity and specifications.* (1) The color additive caramel shall conform in identity and specifications to the requirements of § 73.85(a) (1), (2), and (3) and (b).

(2) The diluents in color additive mixtures for drug use containing caramel shall be limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* Caramel may be used for coloring ingested and topically applied drugs generally in amounts consistent with good manufacturing practice.

(c) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirement of section 706(c) of the act.

§ 73.1095 β-Carotene.

(a) *Identity and specifications.* (1) The color additive β-carotene shall conform in identity and specifications to the requirements of § 73.95(a)(1) and (b).

(2) The diluents in color additive mixtures for drug use containing β-carotene are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* The color additive β-carotene may be safely used in coloring drugs generally, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 15643, Mar. 22, 1977, as amended at 42 FR 33722, July 1, 1977]

§ 73.1100 Cochineal extract; carmine.

(a) *Identity and specifications.* (1) The color additives cochineal extract and carmine shall conform in identity and specifications to the requirements of § 73.100(a) (1) and (2) and (b).

(2) Color additive mixtures for drug use made with carmine and cochineal extract may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* Cochineal extract and carmine may be safely used for coloring ingested and externally applied drugs in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1125 Potassium sodium copper chloropyhllin (chlorophyllin-copper complex).

(a) *Identity.* (1) The color additive potassium sodium copper chlorophyllin is a green to black powder obtained from chlorophyll by replacing the methyl and phytyl ester groups with alkali and replacing the magnesium with copper. The source of the chlorophyll is dehydrated alfalfa.

(2) Color additive mixtures for drug use made with potassium sodium copper chlorophyllin may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Potassium sodium copper chlorophyllin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Moisture, not more than 5.0 percent.
Nitrogen, not more than 5.0 percent.
pH of 1 percent solution, 9 to 11.
Total copper, not less than 4 percent and not more than 6 percent.
Free copper, not more than 0.25 percent.
Iron, not more than 0.5 percent.
Lead (as Pb)), not more than 20 parts per million.
Arsenic (as As), not more than 5 parts per million.
Ratio, absorbance at 405 $m\mu$ to absorbance at 630 $m\mu$, not less than 3.4 and not more than 3.9.
Total color, not less than 75 percent.

(c) *Uses and restrictions.* Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are drugs at a level not to exceed 0.1 percent. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1150 Dihydroxyacetone.

(a) *Identity.* (1) The color additive dihydroxyacetone is 1,3-dihydroxy-2-propanone.

(2) Color additive mixtures for drug use made with dihydroxyacetone may contain only those diluents that are listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Dihydroxyacetone shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter (at 34.6° C. for 3 hours at a pressure of not more than 30 mm. mercury), not more than 0.5 percent.
Residue on ignition, not more than 0.4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Iron (as Fe), not more than 25 parts per million.
1,3-dihydroxy-2-propanone, not less than 98 percent.

(c) *Uses and restrictions.* Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied drugs intended solely or in part to impart a color to the human body. Authorization for this use shall not be construed as waiving any of the requirements of section 505 of the act with respect to the drug in which it is used.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1162 Bismuth oxychloride.

(a) *Identity.* (1) The color additive bismuth oxychloride is a synthetically prepared white or nearly white amorphous or finely crystalline, odorless powder consisting principally of BiOCl.

(2) Color additive mixtures for drug use made with bismuth oxychloride may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive bismuth oxychloride shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Bismuth oxychloride, not less than 98 percent.

(c) *Uses and restrictions.* The color additive bismuth oxychloride may be safely used in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

[42 FR 52394, Sept. 30, 1977]

§ 73.1200 Synthetic iron oxide.

(a) *Identity.* (1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for drug use made with synthetic iron oxide may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring drugs.

(b) *Specifications.* Synthetic iron oxide shall conform to the following specifications, all on an "as is" basis:

Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* The color additive synthetic iron oxide may be safely used to color ingested or topically applied drugs generally subject to the restriction that if the color additive is used in drugs ingested by man the amount consumed in accordance with labeled or prescribed dosages shall not exceed 5 milligrams, calculated as elemental iron, per day.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 706(c) of the act.

§ 73.1298 Ferric ammonium ferrocyanide.

(a) *Identity.* (1) The color additive ferric ammonium ferrocyanide is the blue pigment obtained by oxidizing under acidic conditions with sodium dichromate the acid digested precipitate resulting from mixing solutions of ferrous sulfate and sodium ferrocyanide in the presence of ammonium sulfate. The oxidized product is filtered, washed, and dried. The pigment consists principally of ferric ammonium ferrocyanide with smaller amounts of ferric ferrocyanide and ferric sodium ferrocyanide.

(2) Color additive mixtures for drug use made with ferric ammonium ferrocyanide may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Ferric ammonium ferrocyanide shall conform to the following specifications and shall be free of impurities other than those named to the extent that the other impurities may be avoided by good manufacturing practice:

Oxalic acid or its salts, not more than 0.1 percent.
Water soluble matter, not more than 3 percent.
Water soluble cyanide, not more than 10 parts per million.
Volatile matter, not more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Nickel (as Ni), not more than 200 parts per million.
Cobalt (as Co), not more than 200 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total iron (as Fe corrected for volatile matter), not less than 33 percent and not more than 39 percent.

(c) *Uses and restrictions.* Ferric ammonium ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therfore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 38562, July 29, 1977, as amended at 44 FR 28322, May 15, 1979]

§ 73.1299 Ferric ferrocyanide.

(a) *Identity.* (1) The color additive ferric ferrocyanide is a ferric hexacyanoferrate pigment characterized by the structual formula $Fe_4[Fe(CN)_6]_3 \cdot XH_2O$, which may contain small amounts of ferric sodium ferrocyanide and ferric potassium ferrocyanide.

(2) Color additive mixtures for drug use made with ferric ferrocyanide may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Ferric ferrocyanide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Water soluble cyanide, not more than 10 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Nickel (as Ni), not more than 200 parts per million.
Cobalt (as Co), not more than 200 parts per million.
Mercury (as Hg), not more than 1 part per million.
Oxalic acid, not more than 0.1 percent.
Water soluble matter, not more than 3 percent.
Volatile matter, not more than 10 percent.
Total iron (as Fe corrected for volatile matter), not less than 37 percent and not more than 45 percent.

(c) *Uses and restrictions.* Ferric ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs including those intended for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 706(c) of the act.

(Sec. 706(b), (c), and (d); 74 Stat. 399-403 as amended (21 U.S.C. 376(b), (c), and (d)); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note))

[43 FR 54235, Nov. 21, 1978]

§ 73.1326 Chromium hydroxide green.

(a) *Identity.* (1) The color additive chromium hydroxide green is principally hydrated chromic sesquioxide ($Cr_2O_3 \cdot XH_2O$).

(2) Color additive mixtures for drug use made with chromium hydroxide green may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Chromium hydroxide green shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Water soluble matter, not more than 2.5%.
Chromium in 2% NaOH extract, not more than 0.1% as Cr_2O_3 (based on sample weight).
Boron (as B_2O_3), not more than 8 percent.
Total volatile matter at 1000° C, not more than 20%.
Cr_2O_3 not less than 75%.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Chromium hydroxide green may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom (intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 36451, July 15, 1977, as amended at 42 FR 59852, Nov. 22, 1977]

§ 73.1327 Chromium oxide greens.

(a) *Identity.* (1) The color additive chromium oxide greens is principally chromic sesquioxide (Cr_2O_3).

(2) Color additive mixtures for drug use made with chromium oxide greens may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* the color additive chormium oxide greens shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Chromium in 2% NaOH extract, not more than 0.075% as Cr_2O_3 (based on sample weight).
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 20 parts per million.
Mercury (as Hg), not more than 1 part per million.
Cr_2O_3, not less than 95%.

(c) *Uses and restrictions.* Chromium oxide greens is safe for use in coloring externally applied drugs, including those intended for use in the area of eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from certification pursuant to section 706(c) of the act.

[42 FR 36451, July 15, 1977]

§ 73.1329 Guanine.

(a) *Identity.* (1) The color additive guanine is the crystalline material obtained from fish scales and consists principally of the two purines, guanine and hypoxanthine. The guanine content will vary from 75 to 97 percent, and the hypoxanthine will vary from 3 to 25 percent, depending on the particular fish and tissue from which the crystals are derived.

(2) Color additive mixtures for drug use made with guanine may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive guanine shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Guanine, not less than 75 percent.
Hypoxanthine, not more than 25 percent.
Ash (ignition at 800° C), not more than 2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Assay, not less than 96 percent total purines.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Guanine is safe for use in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from certification pursuant to section 706(c) of the act.

[42 FR 37537, July 22, 1977]

§ 73.1375 Pyrogallol.

(a) *Identity.* The color additive pyrogallol is 1,2,3-trihydroxybenzene.

(b) *Specifications.* Pyrogallol shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Melting point, between 130° and 133° C.
Residue on ignition, not more than 0.1 percent.
Lead (as Pb), not more than 20 p/m (parts per million).
Arsenic (as As), not more than 3 p/m.

(c) *Uses and restrictions.* Pyrogallol may be safely used in combination with ferric ammonium citrate (as listed in § 73.1025), for coloring plain and chromic catgut sutures for use in general and ophthalmic surgery, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The level of the ferric ammonium citrate-pyrogallol complex shall not exceed 3 percent of the total weight of the suture material.

(3) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissues.

(4) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784–1788 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1400 Pyrophyllite.

(a) *Identity.* (1) The color additive pyrophyllite is a naturally occurring mineral substance consisting predominantly of a hydrous aluminum silicate, $Al_2O_3 \cdot 4SiO_2 \cdot H_2O$, intimately mixed with lesser amounts of finely divided silica, SiO_2. Small amounts, usually less than 3 percent, of other silicates, such as potassium aluminum silicate, may be present. Pyrophyllite may be identified and semiquantitatively determined by its characteristic X-ray powder diffraction pattern and by its optical properties.

(2) Color additive mixtures made with pyrophyllite are limited to those listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Pyrophyllite shall conform to the following specifications:

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the pyrophyllite for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* Pyrophyllite may be safely used in amounts consistent with good manufacturing practice to color drugs that are to be externally applied.

(d) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1410 Logwood extract.

(a) *Identity.* The color additive logwood extract is a reddish brown-to-black solid material extracted from the heartwood of the leguminous tree *Haematoxylon campechianum.* The active colorant substance is principally hematein. The latent coloring material is the unoxidized or leuco form of hematein called hematoxylin. The leuco form is oxidized by air.

(b) *Specifications.* Logwood extract shall conform to the following specifications and shall be free from impurities other than those named to the extent that such imnurities may be avoided by good manufacturing practice:

Volatile matter (at 110° C), not more than 15 percent.

Sulfated ash, not more than 20 percent.

Hematein, not less than 5 percent and not more than 20 percent.

Lead (as Pb), not more than 70 parts per million.

Arsenic (as As), not more than 4 parts per million.

Mercury (as Hg), not more than 3 parts per million.

(c) *Use and restrictions.* Logwood extract may be safely used to color nylon 66 (the copolymer of hexamethylenediamine and adipic acid), nylon 6 (the polymer of ϵ-caprolactam), or silk nonabsorable sutures for use in general and ophthalmic surgery subject to the following restrictions:

(1) The quantity of color additive does not exceed 1.0 percent by weight of the suture.

(2) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(3) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the act, is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 52393, Sept. 30, 1977; 43 FR 1490, Jan. 10, 1978]

§ 73.1496 Mica.

(a) *Identity.* (1) The color additive mica is a white powder obtained from the naturally occurring mineral, muscovite mica, consisting predominantly of a potassium aluminum silicate, $K_2Al_4(Al_2Si_6O_{20})(OH)_4$ or, alternatively, $H_2KAl_3(SiO_4)_3$. Mica may be identified and semiquantitatively determined by its characteristic X-ray diffraction pattern and by its optical properties.

(2) Color additive mixtures for drug use made with mica may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Mica shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Fineness, 100 percent shall pass through a 100-mesh sieve.

Loss on ignition at 600-650 °C, not more than 2 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* Mica may be safely used in amounts consistent with good manufacturing practice to color dentifrices and externally applied drugs, including those for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 38561, July 29, 1977, as amended at 52 FR 29665, Aug. 11, 1987]

§ 73.1550 Talc.

(a) *Identity.* (1) The color additive talc is a finely powdered, native, hydrous magnesium silicate sometimes containing a small proportion of aluminum silicate.

(2) Color additive mixtures for drug use made with talc may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) *Specifications.* Talc shall meet the specifications for talc in the United States Pharmacopeia XX (1980) and the following:

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the talc for 15 minutes in 50 milliliters of 0.5*N* hydrochloric acid.

(c) *Uses and restrictions.* Talc may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 15643, Mar. 22, 1977, as amended at 49 FR 10089, Mar. 19, 1984]

§ 73.1575 Titanium dioxide.

(a) *Identity and specifications.* (1) The color additive titanium dioxide shall conform in identity and specifications to the requirements of § 73.575(a)(1) and (b).

(2) Color additive mixtures for drug use made with titanium dioxide may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring drugs, and the following: Silicon dioxide, SiO_2, and/or aluminum oxide, Al_2O_3, as dispersing aids—not more than 2 percent total.

(b) *Uses and restrictions.* The color additive titanium dioxide may be used for coloring ingested and externally applied drugs generally, in amounts consistent with good manufacturing practice. External application includes use in the area of the eye.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of the chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.1645 Aluminum powder.

(a) *Identity.* (1) The color additive aluminum powder shall be composed of finely divided particles of aluminum prepared from virgin aluminum. It is free from admixture with other substances.

(2) Color additive mixtures for external drug use made with aluminum powder may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Aluminum powder shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Fineness, 100 percent shall pass through a 200-mesh screen and 95 percent shall pass through a 325-mesh screen.
Mercury, not more than 1 part per million.
Arsenic, not more than 3 parts per million.
Lead, not more than 20 parts per million.
Aluminum, not less than 99 percent.

(c) *Uses and restrictions.* Aluminum powder is safe for use in externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from certification pursuant to section 706(c) of the act.

[42 FR 38563, July 29, 1977]

§ 73.1646 Bronze powder.

(a) *Identity.* (1) The color additive bronze powder is a very fine metallic powder prepared from alloys consisting principally of virgin electrolytic copper and zinc with small amounts of the virgin metals aluminum and tin. It contains small amounts of stearic or oleic acid as lubricants.

(2) Color additive mixtures for drug use made with bronze powder may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Bronze powder shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Stearic or oleic acid, not more than 5 percent.
Cadmium (as Cd), not more than 15 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Aluminum (as Al), not more than 0.5 percent.
Tin (as Sn), not more than 0.5 percent.
Copper (as Cu), not more than 95 percent and not less than 70 percent.
Zinc (as Zn), not more than 30 percent.

Maximum particle size 45μ (95 percent minimum). Aluminum, zinc, tin, and copper content shall be based on the weight of the dried powder after being thoroughly washed with ether.

(c) *Uses and restrictions.* Bronze powder may be safely used in color externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 33723, July 1, 1977]

§ 73.1647 Copper powder.

(a) *Identity.* (1) The color additive copper powder is a very fine free-flowing metallic powder prepared from virgin electrolytic copper. It contains small amounts of stearic or oleic acid as lubricants.

(2) Color additive mixtures for drug use made with copper powder may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Copper powder shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Stearic or oleic acid, not more than 5 percent.
Cadmium (as Cd), not more than 15 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Copper (as Cu), not less than 95 percent.
Maximum particle size 45μ (95 percent minimum).

(c) *Uses and restrictions.* Copper powder may be safely used in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 33723, July 1, 1977]

§ 73.1991 Zinc oxide.

(a) *Identity.* (1) The color additive zinc oxide is a white or yellow-white amorphous powder manufactured by the French process (described as the indirect process whereby zinc metal isolated from the zinc-containing ore is vaporized and then oxidized). It is principally composed of Zn.

(2) Color additive mixtures for drug use made with zinc oxide may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Zinc oxide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Zinc oxide (as ZnO), not less than 99 percent.
Loss on ignition at 800° C, not more than 1 percent.
Cadmium (as Cd), not more than 15 parts per million.
Mercury (as Hg), not more than 1 part per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 20 parts per million.

(c) *Uses and restrictions.* The color additive zinc oxide may be safely used for coloring externally applied drugs, including those used in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixtues prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from the certifiation pursuant to section 706(c) of the act.

[42 FR 37537, July 22, 1977]

Subpart C—Cosmetics

§ 73.2030 Annatto.

(a) *Identity and specification.* The color additive annatto shall conform in identify and specification to the requirements for annatto extract in § 73.30(a)(1) and (b).

(b) *Use and restriction.* The color additive annatto may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 36994, July 19, 1977]

§ 73.2085 Caramel.

(a) *Identity and specifications.* The color additive caramel shall conform in identity and specifications to the requirements of § 73.85(a)(1), (2), and (3) and (b).

(b) *Uses and restrictions.* Caramel is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirement of section 706(c) of the act.

[46 FR 38501, July 28, 1981]

§ 73.2087 Carmine.

(a) *Identity and specifications.* The color additive carmine shall conform in identity and specifications to the requirements of § 73.100 (a)(2) and (b)(2).

(b) *Use and restrictions.* Carmine may be safely used in cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practices.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 706(c) of the act.

[42 FR 32228, June 24, 1977]

§ 73.2095 β-Carotene.

(a) *Identity and specifications.* The color additive β-carotene shall conform in identity and specifications to the requirements of § 73.95(a)(1) and (b).

(b) *Uses and restrictions.* The color additive β-carotene may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practices.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches therof are exempt from the certification pursuant to section 706(c) of the act.

[42 FR 33722, July 1, 1977]

§ 73.2110 Bismuth citrate.

(a) *Identity.* The color additive bismuth citrate is the synthetically prepared crystalline salt of bismuth and citric acid, consisting principally of $BiC_6H_5O_7$.

(b) *Specifications.* The color additive bismuth citrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that those impurities may be avoided by good manufacturing practice:

Bismuth citrate, not less than 97 percent.
Mercury (as Hg), not more than 1 part per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 20 parts per million.
Volatile matter, not more than 1 percent.

(c) *Uses and restrictions.* The color additive bismuth citrate may be safely used in cosmetics intended for coloring hair on the scalp, subject to the following restrictions:

(1) The amount of bismuth citrate in the cosmetic shall not be in excess of 0.5 percent (w/v).

(2) The cosmetic may not be used for coloring eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling.* (1) The label of the color additive bismuth citrate shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(2) The label of a cosmetic containing the color additive bismuth citrate shall bear, in addition to other information required by law, the following statement, conspicuously displayed thereon:

Keep this product out of children's reach. Do not use on cut or abraded scalp. Do not use to color eyelashes, eyebrows, or hair on parts of the body other than the scalp. Wash hands thoroughly after each use.

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health, and, therefore, batches thereof are exempt from certification requirements of section 706(c) of the act.

(Sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), and (d), and title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note))

[43 FR 44831, Sept. 29, 1978]

§ 73.2120 Disodium EDTA-copper.

(a) *Identity.* The color additive disodium EDTA-copper is disodium [[*N,N'*-1,2- ethanediylbis[*N* - (carboxymethyl) glycinato]] (4-)-$N,N',O,O',O^N,O^{N'}$] cuprate (2-).

(b) *Specifications.* Disodium EDTA-copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Total copper, not less than 13.5 percent.
Total (ethylene-dinitrilo) tetracetic acid, not less than 62.5 percent.
Free copper, not more than 100 parts per million.
Free disodium salt of (ethylene-dinitrilo) tetraacetic acid, not more than 1.0 percent.
Moisture, not more than 15 percent.
Water insoluble matter, not more than 0.2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

(c) *Uses and restrictions.* Disodium EDTA-copper may be safely used in amounts consistent with good manufacturing practices in the coloring of shampoos which are cosmetics.

(d) *Labeling requirements.* The labeling of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 706(c) of the act.

§ 73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity and specifications.* The color additive potassium sodium copper chlorophyllin shall conform in identity and specifications to the requirements of § 73.1125(a)(1) and (b).

(b) *Uses and restrictions.* Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that are cosmetics subject to the following conditions:

(1) It shall not be used at a level in excess of 0.1 percent.

(2) It may be used only in combination with the following substances:

Water.
Glycerin.
Sodium carboxymethylcellulose.

Tetrasodium pyrophosphate.
Sorbitol.
Magnesium phosphate, tribasic.
Calcium carbonate.
Calcium phosphate, dibasic.
Sodium *N*-lauroyl sarcosinate.
Artificial sweeteners that are generally recognized as safe or that are authorized under Subchapter B of this chapter.
Flavors that are generally recognized as safe or that are authorized under Subchapter B of this chapter.
Preservatives that are generally recognized as safe or that are authorized under Subchapter B of this chapter.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.2150 Dihydroxyacetone.

(a) *Identity and specifications.* The color additive dihydroxyacetone shall conform in identity and specifications to the requirements of § 73.1150 (a)(1) and (b).

(b) *Uses and restrictions.* Dihydroxyacetone may be safely used in amounts consistent with good manufacturing practice in externally applied cosmetics intended solely or in part to impart a color to the human body.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 706(c) of the act.

§ 73.2162 Bismuth oxychloride.

(a) *Identity and specifications.* (1) The color additive bismuth oxychloride shall conform in identity and specifications to the requirements of § 73.1162(a)(1) and (b).

(2) Color additive mixtures of bismuth oxychloride may contain the following diluents:

(i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);

(ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Uses and restrictions.* The color additive bismuth oxychloride may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

[42 FR 52394, Sept. 30, 1977]

§ 73.2180 Guaiazulene.

(a) *Identity.* (1) The color additive, guaiazulene, is principally 1,4-dimethyl-7-isopropyl-azulene.

(2) Color additive mixtures of guaiazulene for cosmetic use may contain the following diluent:

Polyethylene glycol-40 castor oil (PEG-40 castor oil).
Saponification No., 60 to 70.
Hydroxyl No., 63 to 78.
Acid No., 2.
Specific gravity, 1.05 to 1.07.

(b) *Specifications.* Guaiazulene shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Melting point, 30.5° C to 31.5° C.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.
Total color, not less than 99 percent.

(c) *Uses and restrictions.* Guaiazulene may be safely used in externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.2190 Henna.

(a) *Identity.* The color additive henna is the dried leaf and petiole of *Lawsonia alba* Lam. (*Lawsonia inermis* L.). It may be identified by its characteristic odor and by characteristic plant histology.

(b) *Specifications.* Henna shall conform to the following specifications:

It shall not contain more than 10 percent of plant material from *Lawsonia alba* Lam. (*Lawsonia inermis* L.) other than the leaf and petiole, and shall be free from admixture with material from any other species of plant.

Moisture, not more than 10 percent.
Total ash, not more than 15 percent.
Acid-insoluble ash, not more than 5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.

(c) *Uses and restrictions.* The color additive henna may be safely used for coloring hair only. It may not be used for coloring the eyelashes or eyebrows, or generally in the area of the eye.

(d) *Labeling.* The label for henna shall bear the information required by § 70.25 of this chapter and the following statements or their equivalent:

"Do not use in the area of the eye."
"Do not use on cut or abraded scalp."

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.2250 Iron oxides.

(a) *Identity.* The color additives iron oxides consist of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(b) *Specifications.* Iron oxides shall conform to the following specifications, all on an "as is" basis:

Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) *Uses and restrictions.* Iron oxides are safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

§ 73.2298 Ferric ammonium ferrocyanide.

(a) *Identity and specifications.* The color additive ferric ammonium ferrocyanide shall conform in identify and specifications to the requirements of § 73.1298 (a)(1) and (b).

(b) *Uses and restrictions.* Ferric ammonium ferrocyanide is safe for use in coloring externally applied cosmetics, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 706(c) of the act.

[42 FR 38562, July 29, 1977, as amended at 43 FR 6939, Feb. 17, 1978]

§ 73.2299 Ferric ferrocyanide.

(a) *Identity and specifications.* The color additive ferric ferrocyanide shall conform in identity and specifications to the requirements of § 73.1299(a)(1) and (b).

(b) *Uses and restrictions.* Ferric ferrocyanide is safe for use in coloring externally applied cosmetics, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification under section 706(c) of the act.

(Sec. 706(b), (c), and (d); 74 Stat. 399-403 as amended (21 U.S.C. 376(b), (c), and (d); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note))

[43 FR 54236, Nov. 21, 1978]

§ 73.2326 Chromium hydroxide green.

(a) *Identity and specifications.* The color additive chromium hydroxide green shall conform in identity and specifications to the requirements of § 73.1326 (a)(1) and (b).

(b) *Uses and restrictions.* Chromium hydroxide green is safe for use in coloring externally applied cosmetics, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

[42 FR 36452, July 15, 1977]

73.2327 Chromium oxide greens.

(a) *Identity and specifications.* The color additive chromium oxide greens shall conform in identify and specifications to the requirements of § 73.1327 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive chromium oxide greens may be safely used in externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 706(c) of the act.

[42 FR 36452, July 15, 1977]

§ 73.2329 Guanine.

(a) *Identity and specifications.* (1) The color additive guanine shall conform in identity and specifications to the requirements of § 73.1329 (a)(1) and (b).

(2) Color additive mixtures of guanine may contain the following diluents:

(i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);

(ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Use and restrictions.* The color additive guanine may be safely used in cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 706(c) of the act.

[42 FR 37537, July 22, 1977]

§ 73.2396 Lead acetate.

(a) *Identity.* The color additive lead acetate is the trihydrate of lead (2+) salt of acetic acid. The color additive has the chemical formula $Pb(OOCCH_3)_2.3H_2O$).

(b) *Specifications.* Lead acetate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Water-insoluble matter, not more than 0.02 percent.
pH (30 percent solution weight to volume at 25° C), not less than 4.7 and not more than 5.8.
Arsenic (as As), not more than 3 parts per million.
Lead acetate, not less than 99 percent.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The color additive lead acetate may be safely used in cosmetics intended for coloring hair on the scalp only, subject to the following restrictions:

(1) The amount of the lead acetate in the cosmetic shall be such that the lead content, calculated as Pb, shall not be in excess of 0.6 percent (weight to volume).

(2) The cosmetic is not to be used for coloring mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling requirements.* (1) The label of the color additive lead acetate shall conform to the requirements of § 170.25 of this chapter, and bear the following statement or equivalent:

> Wash thoroughly if the product comes into contact with the skin.

(2) The label of the cosmetic containing the color additive lead acetate, in addition to other information required by the act, shall bear the following cautionary statement, conspicuously displayed thereon:

> CAUTION: Contains lead acetate. For external use only. Keep this product out of children's reach. Do not use on cut or abraded scalp. If skin irritation develops, discontinue use. Do not use to color mustaches, eyelashes, eyebrows, or hair on parts of the body other than the scalp. Do not get in eyes. Follow instructions carefully and wash hands thoroughly after each use.

(e) *Exemption for certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

(Sec. 706(b), (c), (d), 74 Stat. 399—403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[45 FR 72117, Oct. 31, 1980]

§ 73.2400 Pyrophyllite.

(a) *Identity and specifications.* The color additive pyrophyllite shall conform in identity and specifications to the requirements of § 73.1400 (a)(1) and (b).

(b) *Uses and restrictions.* Pyrophyllite may be safely used for coloring externally applied cosmetics, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The labeling of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to all applicable requirements of law, including the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

§ 73.2496 Mica.

(a) *Identity and specifications.* The color additive mica shall conform in identity and specifications to the requirements of § 73.1496(a)(1) and (b).

(b) *Uses and restrictions.* Mica is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 706(c) of the act.

[42 FR 38561, July 29, 1977]

§ 73.2500 Silver.

(a) *Identity.* (1) The color additive, silver, is a crystalline powder of high purity silver prepared by the reaction of silver nitrate with ferrous sulfate in the presence of nitric, phosphoric and sulfuric acids. Polyvinyl alcohol is used to prevent the agglomeration of crystals and the formation of amorphous silver.

(2) Color additive mixtures of silver may contain only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Specifications.* Silver shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 5 parts per million.

Mercury (as Hg), not more than 1 part per million.

Silver (as Ag), not less than 99.9 percent.

(c) *Uses and restrictions.* The color additive silver may be safely used for coloring fingernail polish at a level not to exceed 1 percent of the final product.

(d) *Labeling.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[44 FR 65974, Nov. 16, 1979]

§ 73.2575 Titanium dioxide.

(a) *Identity and specifications.* The color additive titanium dioxide shall conform in identity and specifications to the requirements on § 73.575 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive titanium dioxide may be safely used in cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

§ 73.2645 Aluminum powder.

(a) *Identity and specifications.* The color additive aluminum powder shall conform in identity and specifications to the requirements of § 73.1645 (a)(1) and (b).

(b) *Uses and restrictions.* Aluminum powder may be safely used in coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 706(c) of the act.

[42 FR 38563, July 29, 1977]

§ 73.2646 Bronze powder.

(a) *Identity and specifications.* The color additive bronze powder shall conform in identity and specifications to the requirements of § 73.1646 (a)(1) and (b).

(b) *Uses and restrictions.* Bronze powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 33724, July 1, 1977]

§ 73.2647 Copper powder.

(a) *Identity and specifications.* The color additive copper powder shall conform in identity and specifications to the requirements of § 73.1647 (a)(1) and (b).

(b) *Uses and restrictions.* Copper powder may be safely used in coloring cosmetics generally, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of the color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 706(c) of the act.

[42 FR 33724, July 1, 1977]

§ 73.2725 Ultramarines.

(a) *Identity.* The color additives, ultramarines (blue, green, pink, red, and violet) are pigments obtained by calcining at temperatures above 700° C. a mixture of kaolin, sulfur, sodium carbonate, silicious matter, sodium sulfate, and carbonaceous matter, but not necessarily all these substances, to produce a single color. The ultramarines are complex sodium aluminum sulfosilicates having a typical formula $Na(AlSiO)S$ with proportions of each element varying with each color.

(b) *Specifications.* The ultramarines shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* The ultramarine pigments may be safely used for coloring externally applied cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* The color additives and any mixtures prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any other information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

§ 73.2775 Manganese violet.

(a) *Identity.* The color additive manganese violet is a violet pigment obtained by reacting phosphoric acid, ammonium dihydrogen orthophosphate, and manganese dioxide at temperatures above 450° F. The pigment is a manganese ammonium pyrophosphate complex having the approximate formula: $\mathrm{Mn\ (III)\ NH_4P_2O_7}$.

(b) *Specifications.* Manganese violet shall conform to the following specifications and shall be free from impurities other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Ash (at 600° C), not less than 81 percent.

Volatile matter at 135° C for 3 hours, not more than 1 percent.

Water soluble substances, not more than 6 percent.

pH of filtrate of 10 grams color additive (shaken occasionally for 2 hours with 100 milliliters of freshly boiled distilled water), not more than 4.7 and not less than 2.5.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, based on Mn content in "as is" sample, not less than 93 percent.

(c) *Uses and restrictions.* Manganese violet is safe for use in coloring cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(d) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification pursuant to section 706(c) of the act.

§ 73.2991 Zinc oxide.

(a) *Identity and specifications.* The color additive zinc oxide shall conform in identity and specifications to the requirements of § 73.1991 (a)(1) and (b).

(b) *Uses and restrictions.* Zinc oxide may be safely used in cosmetics, including cosmetics intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification pursuant to section 706(c) of the act.

[42 FR 37538, July 22, 1977]

Subpart D—Medical Devices

§ 73.3105 1,4-Bis[(2-methylphenyl)amino]-9,10-anthracenedione.

(a) *Identity.* The color additive is 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 6737-68-4).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing 1,4-bis[(2-methylphenyl)amino]-9,10-anthracenedione listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with Subpart E of Part 807 of this chapter, if the device is not subject to premarket approval, or submit and re-

ceive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[49 FR 30066, July 26, 1984]

§ 73.3107 Carbazole violet.

(a) *Identity.* The color additive is carbazole violet (Pigment Violet 23) (CAS Reg. No. 6358-30-1, Colour Index No. 51319).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[53 FR 41324, Oct. 21, 1988]

§ 73.3110 Chlorophyllin-copper complex, oil soluble.

(a) *Identity.* The color additve is chlorophyllin-copper complex, oil soluble. The chlorophyllin is obtained by extraction from a mixture of fescue and rye grasses. The chlorophyll is acid-treated to remove chelated magnesium which is replaced with hydrogen, which is turn is replaced with copper. This mixture is diluted to a 5 percent concentration with a mixture of palm oil, peanut oil, and hydrogenated peanut oil.

(b) *Specifications.* The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Moisture, not more than 0.5 percent.
Nitrogen, not less than 0.2 percent and not more than 0.3 percent.
Total copper, not less than 0.2 percent and not more than 0.4 percent.
Free copper, not more than 200 parts per million.
Lead, not more than 20 parts per million.
Arsenic, not more than 5 parts per million.
Sulfated ash, not more than 2.5 percent.
Total color, not less than 4.5 percent and not more than 5.5 percent.

(c) *Uses and restrictions.* (1) The color additive chlorophyllin-copper complex, oil soluble (5 percent in palm oil, peanut oil, and hydrogenated peanut oil), may be safely used to color polymethylmethacrylate bone cement. Chlorophyllin-copper complex may be used at levels that do not exceed 0.003 percent by weight of the bone cement.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the polymethylmethacrylate bone cement in which chlorophyllin-copper complex, oil soluble, is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[48 FR 56370, Dec. 21, 1983]

§ 73.3110a Chromium-cobalt-aluminum oxide.

(a) *Identity.* The color additive chromium-cobalt-aluminum oxide (Pigment Blue 36) (CAS Reg. No. 68187-11-1, Colour Index No. 77343) shall conform in identity and specifications to the requirements of § 73.1015 (a) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[53 FR 41325, Oct. 21, 1988]

§ 73.3111 Chromium oxide greens.

(a) *Identity and specifications.* The color additive chromium oxide greens (chromic oxide) (CAS Reg. No. 1308-38-9), Color Index No. 77288, shall conform in identity and specifications to the requirements of § 73.1327 (a)(1) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[51 FR 24816, July 9, 1986]

§ 73.3112 C.I. Vat Orange 1.

(a) *Identity.* The color additive is C.I. Vat Orange 1, Colour Index No. 59105.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the contact lens in which the color additive is used. A person intending to introduce a device containing C.I. Vat Orange 1 into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with Subpart E of Part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[50 FR 20407, May 16, 1985]

§ 73.3115 2-[[2,5-Diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol.

(a) *Identity.* The color additive2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol is formed in situ in soft (hydrophilic) contact lenses.

(b) *Uses and restrictions.* The color additive 2-[[2,5-diethoxy-4-[(4-methylphenyl)thio]phenyl]azo]-1,3,5-benzenetriol may be safely used to mark soft (hydrophilic) contact lenses with the letter R or the letter L for identification purposes subject to the following restrictions:

(1) The quantity of the color additive does not exceed 1.1×10^{-7} grams in a soft (hydrophilic) contact lens.

(2) When used as specified in the labeling, there is no measurable migration of the color additive from the contact lens to the surrounding ocular tissue.

(3) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k) and 515 of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[48 FR 22706, May 20, 1983]

§ 73.3117 16,23-Dihydrodinaphtho[2,3-a:2′,3′-i] naphth [2′,3′:6,7] indolo [2,3-c] carbazole-5,10,15,17,22,24-hexone.

(a) *Identity.* The color additive is 16,23-dihydrodinaphtho [2,3- *a*:2′,3′-i] napth [2′,3′:6,7] indolo [2, 3-c] carbazole-5,10, 15,17,22,24-hexone (CAS Reg. No. 2475-33-4), Colour Index No. 70800.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[48 FR 31375, July 8, 1983]

§ 73.3118 N,N′-(9,10-Dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide.

(a) *Identity.* The color additive is *N,N′*-(9,10-dihydro-9,10-dioxo-1,5-anthracenediyl) bisbenzamide (CAS Reg. No. 82-18-8), Colour Index No. 61725.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[48 FR 31375, July 8, 1983]

§ 73.3119 7,16-Dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.

(a) *Identity.* The color additive is 7,16-dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone (CAS Reg. No. 130-20-1), Colour Index No. 69825.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[48 FR 31376, July 8, 1983]

§ 73.3120 16,17-Dimethoxydinaphtho [1,2,3-cd:3',2',1'-lm] perylene-5,10-dione.

(a) *Identity.* The color additive is 16,17-dimethoydinaphtho[1,2,3,-cd:3',2',1'-*lm*]perylene-5,10-dione (CAS Reg. No. 128-58-5), Colour Index No. 59825.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[48 FR 31376, July 8, 1983]

§ 73.3121 Poly(hydroxyethyl methacrylate)-dye copolymers.

(a) *Identity.* The color additives are formed by reacting one or more of the reactive dyes listed in this paragraph with poly(hydroxyethyl methacrylate), so that the sulfate group (or groups) or chlorine substituent of the dye is replaced by an ether linkage to poly(hydroxyethyl methacrylate). The dyes that may be used alone or in combination are

(1) Reactive Black 5 [2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis((4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-tetrasodium salt] (CAS Reg. No. 17095-24-8);

(2) Reactive Blue 21 [copper, (29*H*,31*H*-phthalocyaninato(2-)-$N^{29},N^{30},N^{31},N^{32}$)-, sulfo((4-((2-sulfooxy)ethyl)sulfonyl)phenyl)amino) sulfonyl derivs] (CAS Reg. No. 73049-92-0);

(3) Reactive Orange 78 [2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl) sulfonyl)phenyl)azo)-] CAS Reg. No. 68189-39-9);

(4) Reactive Yellow 15 [benzensulfonic acid, 4-(4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl) sulfonyl)phenyl)azo)-3-methyl-5-oxo-1*H*-pyrazol-1-yl)-] (CAS Reg. No. 60958-41-0);

(5) Reactive Blue No. 19 [2-anthracene-sulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt] (CAS Reg. No. 2580-78-1);

(6) Reactive Blue No. 4 [2-anthracenesulfonic acid, 1-amino-4-(3-((4,6-dichloro-s-triazin-2-yl)amino)-4-sulfoanilino)-9,10-dihydro-9,10-dioxo, disodium salt] (CAS Reg. No. 4499-01-8);

(7) C.I. Reactive Red 11 [5-((4,6-dichloro-1,3,5-triazin-2-yl)amino)-4-hydroxy-3-((1-sulfo-2-naphthalenyl)azo)-2, 7-naphthalenedisulfonic acid, trisodium salt] (CAS Reg. No. 12226-08-3);

(8) C.I. Reactive Yellow 86 [1,3-benzenedisulfonic acid, 4-((5-aminocarbonyl-1-ethyl-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-3-pyridinyl)azo)-6-(4,6-dichloro-1,3,5-triazin-2-yl)amino)-, disodium salt] (CAS Reg. No. 61951-86-8); and

(9) C.I. Reactive Blue 163 [triphenodioxazinedisulfonic acid, 6,13-dichloro-3, 10-bis((4-((4.6-dichloro-1,3,5-triazin-2-yl)amino) sulfophenyl)amino)-, tetrasodium salt] (CAS Reg. No. 72847-56-4).

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) As part of the manufacturing process, the lenses containing the color additives are thoroughly washed to remove unbound reactive dyes.

(3) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing a poly(hydroxyethyl methacrylate)-dye copolymer listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with Subpart E of Part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additives shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of these color additives is not necessary for the protection of the public health, and therefore these color additives are exempt from the certification requirements of section 706(c) of the act.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[49 FR 373, Jan. 4, 1984; 49 FR 5094, Feb. 10, 1984, as amended at 50 FR 9425, Mar. 8, 1985; 50 FR 33338, Aug. 19, 1985; 50 FR 37845, Sept. 18, 1985; 50 FR 45993, Nov. 6, 1985]

§ 73.3122 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one.

(a) *Identity.* The color additive is 4-[(2,4-dimethylphenyl)azo]-2,4-dihydro-5-methyl-2-phenyl-3*H*-pyrazol-3-one (CAS Reg. No. 6407-78-9).

(b) *Uses and restrictions.* (1) The substances listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515 and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[51 FR 11432, Apr. 3, 1986]

§ 73.3123 6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene) benzo[b]thiophen-3 (2H)-one.

(a) *Identity.* The color additive is 6-ethoxy-2-(6-ethoxy-3-oxobenzo [*b*]thien-2(3*H*)-ylidene)benzo[*b*]thiophen-3(2*H*)-one (CAS Reg. No. 3263-31-8), Colour Index No. 73335.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[51 FR 11436, Apr. 3, 1986]

§ 73.3124 Phthalocyanine green.

(a) *Identity.* The color additive is phthalocyanine green (CAS Reg. No. 1328-53-6), Colour Index No. 74260.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[51 FR 11433, Apr. 3, 1986]

§ 73.3125 Iron oxides.

(a) *Identity and specifications.* The color additive iron oxides (CAS Reg. No. 977053-38-5), Color Index No. 77491, shall conform in identity and specifications to the requirements of § 73.2250 (a) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[51 FR 24816, July 9, 1986]

§ 73.3126 Titanium dioxide.

(a) *Identity and specifications.* The color additive titanium dioxide (CAS Reg. No. 13463-67-7), Color Index No. 77891, shall conform in identity and specifications to the requirements of § 73.575(a)(1) and (b).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lenses in which the additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

[51 FR 24816, July 9, 1986]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart A—Foods

Sec.
74.101 FD&C Blue No. 1.
74.102 FD&C Blue No. 2.
74.203 FD&C Green No. 3.
74.250 Orange B.
74.302 Citrus Red No. 2.
74.303 FD&C Red No. 3.
74.340 FD&C Red No. 40.
74.705 FD&C Yellow No. 5.
74.706 FD&C Yellow No. 6.
74.710 D&C Yellow No. 10.

Subpart B—Drugs

74.1101 FD&C Blue No. 1.
74.1102 FD&C Blue No. 2.
74.1104 D&C Blue No. 4.
74.1109 D&C Blue No. 9.
74.1203 FD&C Green No. 3.
74.1205 D&C Green No. 5.
74.1206 D&C Green No. 6.
74.1208 D&C Green No. 8.
74.1254 D&C Orange No. 4.
74.1255 D&C Orange No. 5.
74.1260 D&C Orange No. 10.
74.1261 D&C Orange No. 11.
74.1303 FD&C Red No. 3.
74.1304 FD&C Red No. 4.
74.1306 D&C Red No. 6.
74.1307 D&C Red No. 7.
74.1317 D&C Red No. 17.
74.1321 D&C Red No. 21.
74.1322 D&C Red No. 22.
74.1327 D&C Red No. 27.
74.1328 D&C Red No. 28.
74.1330 D&C Red No. 30.
74.1331 D&C Red No. 31.
74.1333 D&C Red No. 33.
74.1334 D&C Red No. 34.
74.1336 D&C Red No. 36.
74.1339 D&C Red No. 39.
74.1340 FD&C Red No. 40.
74.1602 D&C Violet No. 2.
74.1705 FD&C Yellow No. 5.
74.1706 FD&C Yellow No. 6.
74.1707 D&C Yellow No. 7.
74.1707a Ext. D&C Yellow No. 7.
74.1708 D&C Yellow No. 8.
74.1711 D&C Yellow No. 11.

Sec.

Subpart C—Cosmetics

74.2101 FD&C Blue No. 1.
74.2104 D&C Blue No. 4.
74.2151 D&C Brown No. 1.
74.2203 FD&C Green No. 3.
74.2205 D&C Green No. 5.
74.2206 D&C Green No. 6.
74.2208 D&C Green No. 8.
74.2254 D&C Orange No. 4.
74.2255 D&C Orange No. 5.
74.2260 D&C Orange No. 10.
74.2261 D&C Orange No. 11.
74.2304 FD&C Red No. 4.
74.2306 D&C Red No. 6.
74.2307 D&C Red No. 7.
74.2317 D&C Red No. 17.
74.2321 D&C Red No. 21.
74.2322 D&C Red No. 22.
74.2327 D&C Red No. 27.
74.2328 D&C Red No. 28.
74.2330 D&C Red No. 30.
74.2331 D&C Red No. 31.
74.2333 D&C Red No. 33.
74.2334 D&C Red No. 34.
74.2336 D&C Red No. 36.
74.2340 FD&C Red No. 40.
74.2602 D&C Violet No. 2.
74.2602a Ext. D&C Violet No. 2.
74.2705 FD&C Yellow No. 5.
74.2706 FD&C Yellow No. 6.
74.2707 D&C Yellow No. 7.
74.2707a Ext. D&C Yellow No. 7.
74.2708 D&C Yellow No. 8.
74.2710 D&C Yellow No. 10.
74.2711 D&C Yellow No. 11.

Subpart D—Medical Devices

74.3045 [Phthalocyaninato(2-)] copper.
74.3106 D&C Blue No. 6.
74.3206 D&C Green No. 6.
74.3602 D&C Violet No. 2.
74.3710 D&C Yellow No. 10.
APPENDIX A—THE PROCEDURE FOR DETERMINING ETHER SOLUBLE MATERIAL IN D&C RED NOS. 6 AND 7

AUTHORITY: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

SOURCE: 42 FR 15654, Mar. 22, 1977, unles otherwise noted.

Subpart A—Foods

§ 74.101 FD&C Blue No. 1.

(a) *Identity.* (1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[*p*-[ethyl (*m*-sulfobenzyl) amino]-*α*-(*o*-sulfophenyl) benzylidene] - 2,5 -cyclohexadien - 1 - ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl [4-[*p*-[ethyl(*p*-sulfobenzyl) amino]-*α*-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl [4-[*p*-[ethyl (*o*-sulfobenzyl) amino] - *α* - (*o* -sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*o*-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Blue No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C.) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Leuco base, not more than 5 percent.

Sum of *o*-, *m*-, and *p*-sulfobenzaldehydes, not more than 1.5 percent.

N-ethyl, *N*-(*m*-sulfobenzyl) sulfanilic acid, not more than 0.3 percent.

Subsidiary colors, not more than 6.0 percent.

Chromium (as Cr), not more than 50 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Blue No. 1 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.102 FD&C Blue No. 2.

(a) *Identity.* (1) The color additive FD&C Blue No. 2 is principally the disodium salt of 2-(1,3-dihydro-3-oxo-5-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 860–22–0) with smaller amounts of the disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 54947–75–0) and the sodium salt of 2-(1,3-dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid (CAS Reg. No. 605–18–5). Additionally, FD&C Blue No. 2 is obtained by heating indigo (or indigo paste) in the presence of sulfuric acid. The color additive is isolated and subjected to purification procedures. The indigo (or indigo paste) used above is manufactured by the fusion of *N*-phenylglycine (prepared from aniline and formaldehyde) in a molten mixture of sodamide and sodium and potassium hydroxides under ammonia pressure. The indigo is isolated and subjected to purification procedures prior to sulfonation.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Blue No. 2 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive FD&C Blue No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135° C (275° F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

5-Sulfoanthranilic acid, not more than 0.2 percent.

Disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2*H*-indol-2-ylidene)-2,3-dihydro-3-

oxo-1*H*-indole-5-sulfonic acid, not more than 18 percent.
Sodium salt of 2-(1,3-dihydro-3-oxo-2*H*-indol-2-ylidene)-2,3-dihydro-3-oxo-1*H*-indole-5-sulfonic acid, not more than 2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive FD&C Blue No. 2 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

[48 FR 5260, Feb. 4, 1983]

§ 74.203 FD&C Green No. 3.

(a) *Identity.* (1) The color additive FD&C Green No. 3 is principally the inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide (CAS Reg. No. 2353-45-9); with smaller amounts of the isomeric inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide; of *N*-ethyl-*N*-[4-[[4-[ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide and of *N*-ethyl-*N*-[4-[[4-[ethyl[(2-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide. Additionally, FD&C Green No. 3 is manufactured by the acid catalyzed condensation of one molecule of 2-formyl-5-hydroxybenzenesulfonic acid with two molecules from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzensulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid or with dichromate and acid to form the dye. The intermediate 2-formyl-5-hydroxybenzenesulfonic acid is prepared by the potassium permanganate oxidation of 2,2'-(1,2-ethenediyl)-bis(5-aminobenzenesulfonic acid) to sodium 5-amino-2-formylbenzenesulfonate. This amine is diazotized and the resulting diazonium salt is hydrolyzed to the desired 2-formyl-5-hydroxybenzenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Green No. 3 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring food.

(b) *Specifications.* The color additive FD&C Green No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135° C (275° F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of 2-,3-,4-formylbenzenesulfonic acids, sodium salts, not more than 0.5 percent.
Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl] benzenesulfonic acid, disodium salts, not more than 0.3 percent.
2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5 percent.
Subsidiary colors, not more than 6 percent.

Chromium (as Cr), not more than 50 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 10 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

[47 FR 52143, Nov. 19, 1982; 47 FR 56489, Dec. 17, 1982]

§ 74.250 Orange B.

(a) *Identity.* (1) The color additive Orange B is principally the disodium salt of 1-(4-sulfophenyl)-3-ethylcarboxy-4-(4-sulfonaphthylazo)-5-hydroxypyrazole.

(2) The diluents in color additive mixtures for food use containing Orange B are limited to those listed in Part 73 of this chapter as safe and suitable in color additive mixtures for coloring foods.

(b) *Specifications.* Orange B shall conform to the following specifications:

Volatile matter (at 135° C.), not more than 6.0 percent.

Chlorides and sulfates (calculated as the sodium salts), not more than 7.0 percent.

Water insoluble matter, not more than 0.2 percent.

1-(4-Sulfophenyl)-3-ethylcarboxy-5-hydroxypyrazolone and 1-(4-sulfophenyl)-3-carboxy-5-hydroxypyrazolone, not more than 0.7 percent.

Naphthionic acid, not more than 0.2 percent.

Phenylhydrazine-*p*-sulfonic acid, not more than 0.2 percent.

The trisodium salt of 1-(4-sulfophenyl)-3-carboxy-4-(4-sulfonaphthylazo)-5-hydroxypyrazole, not more than 6.0 percent.

Other subsidiary dyes, not more than 1.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* Orange B may be safely used for coloring the casings or surfaces of frankfurters and sausages subject to the restriction that the quantity of the color additive does not exceed 150 parts per million by weight of the finished food.

(d) *Labeling requirements.* The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Orange B shall be certified in accordance with regulations promulgated under Part 80 of this chapter.

§ 74.302 Citrus Red No. 2.

(a) *Identity.* (1) The color additive Citrus Red No. 2 is principally 1-(2,5-dimethoxyphenylazo)-2-naphthol.

(2) The following diluents may be used in aqueous suspension, in the percentages specified, to facilitate application to oranges in accordance with paragraph (c)(1) of this section:

(i) Suitable diluents used in accordance with § 73.1(a) of this chapter.

(ii) Volatile solvents that leave no residue after application to the orange.

(iii) Salts of fatty acids meeting the requirements of § 172.863 of this chapter.

(iv) Sodium tripolyphosphate, not more than 0.05 percent.

(b) *Specifications.* Citrus Red No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100° C.), not more than 0.5 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Uncombined intermediates, not more than 0.05 percent.

Subsidiary dyes, not more than 2.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Total color, not less than 98 percent.

(c) *Uses and restrictions.* (1) Citrus Red No. 2 shall be used only for coloring the skins of oranges that are not intended or used for processing (or if so used are designated in the trade as "Packinghouse elimination") and that meet minimum maturity standards established by or under the laws of the States in which the oranges are grown.

(2) Oranges colored with Citrus Red No. 2 shall bear not more than 2.0 parts per million of such color additive, calculated on the basis of the weight of the whole fruit.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter. To meet the requirements of § 70.25 (b) and (c) of this chapter the label shall bear:

(1) The statement (or its equivalent) "To be used only for coloring skins of oranges."

(2) Directions for use to limit the amount of the color additive to not more than 2.0 parts per million, calculated on the basis of the weight of the whole fruit.

(e) *Certification.* All batches of Citrus Red No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.303 FD&C Red No. 3.

(a) *Identity.* (1) The color additive FD&C Red No. 3 is principally the monohydrate of 9 (*o*-carboxyphenyl)-6-hydroxy 2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower imdinated fluoresceins.

(2) Color additive mixtures for food use made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Red No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C.) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

Unhalogenated intermediates, total not more than 0.1 percent.

Sodium iodide, not more than 0.4 percent.

Triiodoresorcinol, not more than 0.2 percent.

2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.

Monoiodofluoresceins not more than 1.0 percent.

Other lower iodinated fluoresceins, not more than 9.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 87.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring foods generally (including dietary supplements) in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.340 FD&C Red No. 40.

(a) *Identity.* (1) The color additive FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Red No. 40 may con-

tain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(3) The listing of this color additive includes lakes prepared as described in § 82.51 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 of this chapter.

(b) *Specifications.* FD&C Red No. 40 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C.) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl) azo] -8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, not more than 1.0 percent.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3 percent.

4-Amino-5-methoxy-*o*-toluenesulfonic acid, not more than 0.2 percent.

Disodium salt of 6,6′-oxybis (2-naphthalene-sulfonic acid), not more than 1.0 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85.0 percent.

(c) *Uses and restrictions.* FD&C Red No. 40 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.705 FD&C Yellow No. 5.

(a) *Identity.* (1) The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[4-sulfophenyl-azo]-1*H*-pyrazole-3-carboxylic acid (CAS Reg. No. 1934-21-0). To manufacture the additive, 4-amino-benzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(2) Color additive mixtures for food use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* FD&C Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

4,4′-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.

4-[(4′,5-Disulfo[1,1′-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.

Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.
4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.
4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.
4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.
4-Aminoazobenzene, not more than 75 parts per billion.
4-Aminobiphenyl, not more than 5 parts per billion.
Aniline, not more than 100 parts per billion.
Azobenzene, not more than 40 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent

(c) *Uses and restrictions.* FD&C Yellow No. 5 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) Foods for human use that contain FD&C Yellow No. 5, including butter, cheese, and ice cream, shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive as FD&C Yellow No. 5 among the list of ingredients.

(e) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 501, 502, 701, 706(b), (c), and (d), 52 Stat. 1049-1051 as amended, 1055-1056 as amended, 74 Stat. 399-403 (21 U.S.C. 351, 352, 371, 376 (b), (c), and (d)))

[42 FR 15654, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979, as amended at 44 FR 37220, June 26, 1979; 51 FR 24519, July 7, 1986]

§ 74.706 FD&C Yellow No. 6.

(a) *Identity.* (1) The color additive FD&C Yellow No. 6 is principally the disodium salt of 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid (CAS Reg. No. 2783-94-0). The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid (CAS Reg. No. 50880-65-4) may be added in small amounts. The color additive is manufactured by diazotizing 4-aminobenzenesulfonic acid using hydrochloric acid and sodium nitrite or sulfuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulfonic acid. The dye is isolated as the sodium salt and dried. The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid which may be blended with the principal color is prepared in the same manner except the diazo benzenesulfonic acid is coupled with 3-hydroxy-2,7-naphthalenedisulfonic acid.

(2) Color additive mixtures for food use made with FD&C Yellow No. 6 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive FD&C Yellow No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water insoluble matter, not more than 0.2 percent.

Sodium salt of 4-aminobenzenesulfonic acid, not more than 0.2 percent.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3 percent.

Disodium salt of 6,6′-oxybis[2-naphthalenesulfonic acid], not more than 1 percent.

Disodium salt of 4,4′-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1 percent.

Sum of the sodium salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid, not more than 1 percent.

Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries, not more than 5 percent.

4-Aminoazobenzene, not more than 50 parts per billion.

4-Aminobiphenyl, not more than 15 parts per billion.

Aniline, not more than 250 parts per billion.

Azobenzene, not more than 200 parts per billion.

Benzidine, not more than 1 part per billion.

1,3-Diphenyltriazene, not more than 40 parts per billion.

1-(Phenylazo)-2-naphthalenol, not more than 10 parts per million.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 87 percent.

(c) *Uses and restrictions.* The color additive FD&C Yellow No. 6 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of §70.25 of this chapter.

(2) [Reserved]

(e) *Certification.* All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986, as amended at 52 FR 21508, June 8, 1987; 53 FR 49138, Dec. 6, 1988]

Effective Date Note: At 53 FR 49138, Dec. 6, 1988, § 74.706(d)(2) was suspended, effective December 6, 1988. For the convenience of the user, the suspended text follows.

§ 74.706 FD&C Yellow No. 6.

* * * * *

(d) * * *

(2) Foods for human use that contain FD&C Yellow No. 6, including butter, cheese, and ice cream, shall specifically declare the presence of FD&C Yellow No. 6 by listing the color additive as FD&C Yellow No. 6 among the list of ingredients.

* * * * *

Subpart 3—Drugs

§ 74.1101 FD&C Blue No. 1.

(a) *Identity.* (1) For ingested drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of § 74.101(a)(1).

(2) For externally applied drugs, the color additive FD&C Blue No. 1 shall conform in identity to the requirements of § 74.2101(a).

(3) Color additive mixtures for drug use made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive FD&C Blue No. 1 for use in coloring drugs generally shall conform in specifications to the requirements of § 74.101(b).

(c) *Uses and restrictions.* The color additive FD&C Blue No. 1 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in Part 80 of this chapter.

[47 FR 42565, Sept. 28, 1982]

§ 74.1102 FD&C Blue No. 2.

(a) *Identity.* (1) The color additive FD&C Blue No. 2 shall conform in identity to the requirements of § 74.102(a)(1).

(2) Color additive mixtures for use in ingested drugs made with FD&C Blue No. 2 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* (1) The color additive FD&C Blue No. 2 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135° C (275° F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

Isomeric colors, not more than 18 percent.

Lower sulfonated subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85 percent.

(2) The color additive FD&C Blue No. 2 for use in coloring ingested drugs shall conform to the specifications in § 74.102(b).

(c) *Uses and restrictions.* (1) The color additive FD&C Blue No. 2 may be safely used for coloring nylon (the copolymer of adipic acid and hexamethylene diamine) surgical sutures for use in general surgery subject to the following restrictions:

(i) The quantity of color additive does not exceed 1 percent by weight of the suture.

(ii) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(iii) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissues.

(iv) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, is in effect for it.

(2) The color additive FD&C Blue No. 2 may be safely used for coloring ingested drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[48 FR 5260, Feb. 4, 1983, as amended at 49 FR 10090, Mar. 19, 1984]

§ 74.1104 D&C Blue No. 4.

(a) *Identity.* (1) The color additive D&C Blue No. 4 is principally the diammonium salt of ethyl[4-[*p*[ethyl(*m*-sulfobenzyl)ami-no]-α-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene] (*m*-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric diammonium salts of ethyl [4-[*p*-[ethyl(*p*-sulfobenzyl) amino]-α-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene](*p*-sulfobenzyl) ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl (*o*-sulfobenzyl)amino]-α-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (*o*-sulfobenzyl) ammonium hydroxide inner salt.

(2) Color additive mixtures for use in externally applied drugs made with D&C Blue No. 4 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Blue No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of *o*-, *m*, and *p*-sulfobenzaldehydes, ammonium salt, not more than 1.5 percent.
N-ethyl, N-(*m*-sulfobenzyl) sulfanilic acid ammonium salt, not more than 0.3 percent.
Subsidiary colors, not more than 6 percent.
Chromium (as Cr), not more than 50 parts per million.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* D&C Blue No. 4 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1109 D&C Blue No. 9.

(a) *Identity.* The color additive D&C Blue No. 9 is principally 7,16-dichloro-6,15-dihydro-5,9,14,18-anthrazinetetrone.

(b) *Specifications.* D&C Blue No. 9 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C.), not more than 3 percent.
Matter extractable by alcoholic HCl (0.1 ml of concentrated hydrochloric acid per 50 ml of 95 percent ethyl alcohol), not more than 1 percent.
2-Amino anthraquinone, not more than 0.2 percent.
Organically combined chlorine in pure dye, 13.0-14.8 percent.
Lead (as Pb), not more than 20 p/m.
Arsenic (as As), not more than 3 p/m.
Total color, not less than 97 percent.

(c) *Uses and restrictions.* D&C Blue No. 9 may be safely used for coloring cotton and silk surgical sutures, including sutures for ophthalmic use, subject to the following restrictions:

(1) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(2) The quantity of the color additive does not exceed 2.5 percent by weight of the suture.

(3) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissue.

(4) If the suture is a new drug, a new-drug application approved pursuant to section 505 of the act is in effect for it.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 9 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 15654, Mar. 22, 1977, as amended at 49 FR 10090, Mar. 19, 1984]

§ 74.1203 FD&C Green No. 3.

(a) *Identity and specifications.* (1) The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Green No. 3 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

[47 FR 52144, Nov. 19, 1982]

§ 74.1205 D&C Green No. 5.

(a) *Identity.* (1) The color additive D&C Green No. 5 is principally the disodium salt of 2,2'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis-[5-methylbenzenesulfonic acid] (CAS Reg. No. 4403-90-1).

(2) Color additive mixtures for use in drugs made with D&C Green No. 5 may contain only those diluents that are suitable and those that are listed in Part 73 of this chapter for use in color additive mixtures for coloring drugs.

(b) *Specifications.* (1) D&C Green No. 5 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.
Water insoluble matter, not more than 0.2 percent.
1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
2-Amino-*m*-toluenesulfonic acid, not more than 0.2 percent.
Subsidiary colors, not more than 5 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 80 percent.

(2) D&C Green No. 5 for use in coloring drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 20 percent.
Water-insoluble matter, not more than 0.2 percent.
1,4-Dihydroxyanthraquinone, not more than 0.2 percent.
Sulfonated toluidines, total not more than 0.2 percent.
p-Toluidine, not more than 0.0015 percent.
Sum of monosulfonated D&C Green No. 6 and Ext. D&C Violet No. 2, not more than 3 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 80 percent.

(c) *Use and restrictions.* (1) D&C Green No. 5 may be safely used to color nylon 66 (the copolymer of adipic acid and hexamethylenediamine) and/or nylon 6[poly-(e-caprolactam)]nonabsorbable surgical sutures for use in general surgery, subject to the following restrictions:

(i) The quantity of color additive does not exceed 0.6 percent by weight of the suture.

(ii) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(iii) If the suture is a new drug, an approved new drug application, under section 505 of the act, is in effect for it.

(2) D&C Green No. 5 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

[47 FR 24284, June 4, 1982; 47 FR 27551, June 25, 1982]

§ 74.1206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 is 1,4-bis[(4-methylphenyl)amino]-9,10-anthracenedione (CAS. Reg. No. 128-80-3).

(b) *Specifications.* The color additive D&C Green No. 6 for use in coloring externally applied drugs shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135 °C), not more than 2.0 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 1.5 percent.

p-Toluidine, not more than 0.1 percent.

1,4-Dihydroxyanthraquinone, not more than 0.2 percent.

1-Hydroxy-4-[(4-methylphenyl)amino]-9, 10-anthracenedione, not more than 5.0 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* The color additive D&C Green No. 6 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations promulgated under Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[42 FR 15654, Mar. 22, 1977, as amended at 47 FR 14146, Apr.2, 1982; 47 FR 24278, June 4, 1982; 51 FR 9784, Mar. 21, 1986]

§ 74.1208 D&C Green No. 8.

(a) *Identity.* (1) The color additive D&C Green No. 8 is principally the trisodium salt of 8-hydroxy-1,3,6-pyrene-trisulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Green No. 8 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Green No. 8 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

Volatile matter (at 135° C), not more than 15 percent.

Water-insoluble matter, not more than 0.2 percent.

Chlorides and sulfates (calculated as sodium salt), not more than 20 percent.

The trisodium salt of 1,3,6-pyrenetrisulfonic acid, not more than 6 percent.

The tetrasodium salt of 1,3,6,8-pyrenetetrasulfonic acid, not more than 1 percent.

Pyrene, not more than 0.2 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 65 percent.

(c) *Uses and restrictions.* D&C Green No. 8 may be safely used in externally applied drugs in amounts not exceeding 0.01 percent by weight of the finished product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 8 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1254 D&C Orange No. 4.

(a) *Identity.* (1) the color additive D&C Orange No. 4 is principally the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Orange No. 4 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Orange No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice.

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

2-Naphthol, not more than 0.4 percent.

Sulfanilic acid, sodium salt, not more than 0.2 percent.
Subsidiary colors, not more than 3 percent.
4,4'-(Diazoamino)-dibenzenesulfonic acid, not more than 0.1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions.* D&C Orange No. 4 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

[42 FR 52396, Sept. 30, 1977, as amended at 43 FR 14642, Apr. 7, 1978; 46 FR 8461, Jan. 27, 1981]

§ 74.1255 D&C Orange No. 5.

(a) *Identity.* (1) the color additive D&C Orange No. 5 is a mixture consisting principally the sodium salt of 4',5'-dibromofluorescein (CAS Reg. No. 596-03-2) and 2',4',5'-tribromofluorescein (CAS Reg. No. 25709-83-5) and 2',4',5',7'-tetrabromofluorescein (CAS Reg. No. 15086-94-9). D&C Orange No. 5 is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Orange No. 5 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Orange No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice.

4',5'-dibromofluorescein, not less than 50 percent and not more than 65 percent.
2',4',5'-tribromofluorescein, not less than 30 percent and not more than 40 percent.
2',4',5',7'-tetrabromofluorescein, not more than 10 percent.
Sum of 2',4'-dibromofluorescein and 2',5'-dibromofluorescein, not more than 2 percent.
4'-Bromofluorescein, not more than 2 percent.
Fluorescein, not more than 1 percent.
Phthalic acid, not more than 1 percent.
2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Brominated resorcinol, not more than 0.4 percent.
Sum of volatile matter (at 135° C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.
Insoluble matter (alkaline solution), not more than 0.3 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Orange No. 5 may be safely used for coloring mouthwashes and dentifrices that are ingested drugs in amounts consistent with current good manufacturing practice. D&C Orange No. 5 may be safely used in externally applied drugs in amounts not exceeding 5 milligrams per daily dose of the drug.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

[47 FR 44635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

§ 74.1260 D&C Orange No. 10.

(a) *Identity.* (1) The color additive D&C Orange No 10 is a mixture consisting principally of 4',5'-diiodofluorescein, 2',4',5'-triiodofluorescein, and 2',4',5',7'-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 10 may contain only those diluents listed

in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Orange No. 10 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and halides and sulfates (calculated as sodium salts), not more than 8 percent.
Insoluble matter (alkaline solution), not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.
2-[3′,5′-Diiodo-2′,4′-dihydroxybenzoyl] benzoic acid, not more than 0.5 percent.
Fluorescein, not more than 1 percent.
4′-Iodofluorescein, not more than 3 percent.
2′,4′-Diiodofluorescein and 2′,5′-diiodofluorescein, not more than 2 percent.
2′,4′,5′-Triiodofluorescein, not more than 35 percent.
2′,4′,5′,7′-Tetraiodofluorescein, not more than 10 percent.
4′,5′-Diiodofluorescein, not less than 60 percent and not more than 95 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 10 shall be certified in accordance with regulations in Part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

§ 74.1261 D&C Orange No. 11.

(a) *Identity.* (1) The color additive D&C Orange No. 11 is a mixture consisting principally of the disodium salts of 4′,5′-diiodofluorescein, 2′,4′,5′-triiodofluorescein and 2′,4′,5′,7′-tetraiodofluorescein.

(2) Color additive mixtures for drug use made with D&C Orange No. 11 may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive D&C Orange No. 11 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and halides and sulfates (calculated as sodium salts), not more than 8 percent.
Water-insoluble matter, not more than 0.5 percent.
Phthalic acid, not more than 0.5 percent.
2-[3′,5′-Diiodo-2′,4′-dihydroxybenzoyl] benzoic acid, sodium salt, not more than 0.5 percent.
Fluorescein, disodium salt, not more than 1 percent.
4′-Iodofluorescein, disodium salt, not more than 3 percent.
2′,4′-Diiodofluorescein and 2′,5′-diiodofluorescein, not more than 2 percent.
2′,4′,5′-Triiodofluorescein, not more than 35 percent.
2′,4′,5′,7′-Tetraiodofluorescein, disodium salt, not more than 10 percent.
4′,5′-Diiodofluorescein, disodium salt, not less than 60 percent and not more than 95 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 92 percent.

(c) *Uses and restrictions.* D&C Orange No. 11 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

[46 FR 18953, Mar. 27, 1981]

§ 74.1303 FD&C Red No. 3.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 3

shall conform in identity and specifications to the requirements of § 74.303(a)(1) and (b).

(2) Color additive mixtures for ingested drug used made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring ingested drugs.

(b) *Uses and restrictions.* FD&C Red No. 3 may be safely used for coloring ingested drugs in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1304 FD&C Red No. 4.

(a) *Identity.* (1) The color additive FD&C Red No. 4 is principally the disodium salt of 3-[(2,4-dimethyl-5-sulfophenyl)azo] -4-hydroxy-1-naphthalenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with FD&C Red No. 4 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* FD&C Red No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C.) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
5-Amino-2,4-dimethyl-1-benzenesulfonic acid, sodium salt, not more than 0.2 percent.
4-Hydroxy-1-naphthalenesulfonic acid, sodium salt, not more than 0.2 percent.
Subsidiary colors, not more than 2 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions.* FD&C Red No. 4 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Red No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1306 D&C Red No. 6.

(a) *Identity.* (1) The color additive D&C Red No. 6 is principally the disodium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid (CAS Reg. No. 5858-81-1). To manufacture the additive, 2-amino-5-methylbenzenesulfonic acid is diazotized with hydrochloric acid and sodium nitrite. The diazo compound is coupled in alkaline medium with 3-hydroxy-2-naphthalenecarboxylic acid. The resulting dye precipitates as the disodium salt.

(2) Color additive mixtures for drug use made with D&C Red No. 6 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Red No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.
Ether-soluble matter, passes test entitled "The Procedure for Determining Ether-Soluble Material in D&C Red Nos. 6 and 7," which is an Appendix A to Part 74.
2-Amino-5-methylbenzenesulfonic acid, sodium salt, not more than 0.2 percent.
3-Hydroxy-2-naphthalenecarboxylic acid, sodium salt, not more than 0.4 percent.
3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic acid, sodium salt, not more than 0.5 percent.

p-Toluidine, not more than 15 parts per million.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 90 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 57687, Dec. 28, 1982]

§ 74.1307 D&C Red No. 7.

(a) *Identity.* (1) The color additive D&C Red No. 7 is principally the calcium salt of 3-hydroxy-4-[(4-methyl-2-sulfophenyl)azo]-2-naphthalenecarboxylic acid (CAS Reg. No. 5281-04-9). To manufacture the additive, 2-amino-5-methylbenzenesulfonic acid is diazotized with hydrochloric acid and sodium nitrite. The diazo compound is coupled in alkaline medium with 3-hydroxy-2-naphthalenecarboxylic acid and the resulting dye converted to the calcium salt with calcium chloride.

(2) Color additive mixtures for drug use made with D&C Red No. 7 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Red No. 7 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.

Ether-soluble matter, passes test entitled "The Procedure for Determining Ether-soluble Material in D&C Red Nos. 6 and 7," which is an Appendix A to Part 74.

2-Amino-5-methylbenzenesulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthalenecarboxylic acid, calcium salt, not more than 0.4 percent.

3-Hydroxy-4-[(4-methylphenyl)azo]-2-naphthalenecarboxylic acid, calcium salt, not more than 0.5 percent.

p-Toluidine, not more than 15 parts per million.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 90 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 7 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 57687, Dec. 28, 1982]

§ 74.1317 D&C Red No. 17.

(a) *Identity.* (1) The color additive D&C Red No. 17 is principally 1-[[4-(phenylazo)phenyl]azo]-2-naphthalenol.

(2) Color additive mixtures for drug use made with D&C Red No. 17 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 17 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C), not more than 5 percent.
Matter insoluble in both toluene and water (color additive mixed in toluene and the resultant residue isolated and mixed with water to obtain the matter insoluble in both toluene and water), not more than 0.5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Aniline, not more than 0.2 percent.
4-Aminoazobenzene, not more than 0.1 percent.
2-Naphthol, not more than 0.2 percent.
1-(Phenylazo)-2-naphthol, not more than 3 percent.
1-[[2-(phenylazo) phenyl]azo]-2-naphthalenol, not more than 2 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Red No. 17 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in Part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 42 FR 27225, May 27, 1977]

§ 74.1321 D&C Red No. 21.

(a) *Identity.* (1) The color additive D&C Red No. 21 is principally 2′,4′,5′,7′-tetrabromofluorescein (CAS Reg. No. 15086-94-9), and may contain smaller amounts of 2′,4′,5′-tribromofluorescein (CAS Reg. No. 25709-83-5) and 2′,4′,7′-tribromofluorescein (CAS Reg. No. 25709-84-6). The color additive is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. The fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 21 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Red No. 21 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135°C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.
Insoluble matter (alkaline solution), not more than 0.5 percent.
Phthalic acid, not more than 1 percent.
2-(3,5-Dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
2′,4′,5′,7′-Tetrabromofluorescein, ethyl ester, not more than 1 percent.
Brominated resorcinol, not more than 0.4 percent.
Fluorescein, not more than 0.2 percent.
Sum of mono- and dibromofluoresceins, not more than 2 percent.
Tribromofluoresceins, not more than 11 percent.
2′,4′,5′,7′-Tetrabromofluorescein, not less than 87 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 21 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 21 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376 note))

[47 FR 53846, Nov. 30, 1982]

§ 74.1322 D&C Red No. 22.

(a) *Identity.* (1) The color additive D&C Red No. 22 is principally the disodium salt of 2′,4′,5′7′-tetrabromofluorescein (CAS Reg. No. 17372-87-1) and may contain smaller amounts of the disodium salts of 2′,4′,5′-tribromofluorescein and 2′,4′,7′-tribromofluorescein. The color additive is manufactured by alkaline hydrolysis of 2′,4′,5′,7′-tetrabromofluorescein. 2′,4′,5′,7′-Tetrabromofluorescein is manufactured by brominating fluorescein with elemental bromine. The fluorescein is manufactured by the acid condensation of resorcinol and phthalic acid or its anhydride. Fluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with Red No. 22 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Red No. 22 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135°C) and halides and sulfates (calculated as soduim salts), not more than 10 percent.

Water-insoluble matter not more than 0.5 percent.

Disodium salt of phthalic acid, not more than 1 percent.

Sodium salt of 2-(3,5-Dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.5 percent.

2′,4′,5′,7′-Tetrabromofluorescein, ethyl ester, not more than 1 percent.

Brominated resorcinol, not more than 0.4 percent.

Sum of disodium salts of mono- and dibromofluoresceins, not more than 2 percent.

Sum of disodium salts of tribromofluoresceins, not more than 25 percent.

Disodium salt of 2′,4′,5′,7′-Tetrabromofluorescein, not less than 72 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 90 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 22 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 22 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 53846, Nov. 30, 1982]

§ 74.1327 D&C Red No. 27.

(a) *Identity.* (1) The color additive D&C Red No. 27 is principally 2′,4′,5′,7′-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 13473-26-2). The color additive is manufactured by brominating 4,5,6,7-tetrachlorofluorescein with elemental bromine. The 4,5,6,7-tetrachlorofluorescein is manufactured by the acid condensation of resorcinol and tetrachlorophthalic acid or its anhydride. The 4,5,6,7-tetrachlorofluorescein is isolated and partially purified prior to bromination.

(2) Color additive mixtures for drug use made with D&C Red No. 27 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 27 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135° C) and halides and sulfates (calculated as sodium salts), not more than 10 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Tetrachlorophthalic acid, not more than 1.2 percent.

Brominated resorcinol, not more than 0.4 percent.

2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl) benzoic acid, not more than 0.7 percent.

2′,4′,5′,7′-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent.

Lower halogenated subsidiary colors, not more than 4 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Red No. 27 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 27 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 42567, Sept. 28, 1982; 47 FR 51106, Nov. 12, 1982]

§ 74.1328 D&C Red No. 28.

(a) *Identity.* (1) The color additive D&C Red No. 28 is principally the disodium salt of 2′,4′,5′,7′-tetrabromo-4,5,6,7-tetrachlorofluorescein (CAS Reg. No. 18472-87-2) formed by alkaline hydrolysis of the parent tetrabromotetrachlorofluorescein.

(2) Color additive mixtures for drug use made with D&C Red No. 28 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 28 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter (at 135° C) and halides and sulfates (calculated as sodium salts), not more than 15 percent.

Insoluble matter (alkaline solution), not more than 0.5 percent.

Tetrachlorophthalic acid, not more than 1.2 percent.

Brominated resorcinol, not more than 0.4 percent.

2,3,4,5-Tetrachloro-6-(3,5-dibromo-2,4-dihydroxybenzoyl)benzoic acid, not more than 0.7 percent.

2′,4′,5′,7′-Tetrabromo-4,5,6,7-tetrachlorofluorescein, ethyl ester, not more than 2 percent.

Lower halogenated subsidiary colors, not more than 4 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

(c) *Uses and restrictions.* D&C Red No. 28 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 28 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 42568, Sept. 28, 1982]

§ 74.1330 D&C Red No. 30.

(a) *Identity.* (1) The color additive D&C Red No. 30 is principally 6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[*b*]thien-2(3*H*)-ylidene)-4-methyl-benzo[*b*]thiophen-3(2*H*)-one (CAS Reg. No. 2379-74-0).

(2) Color additive mixtures for drug use made with D&C Red No. 30 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 30 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter (at 135° C), not more than 5 percent.
Chlorides and sulfates (calculated as sodium salts), not more than 3 percent.
Matter soluble in acetone, not more than 5 percent.
Total color, not less than 90 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.

(c) *Uses and restrictions.* D&C Red No. 30 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 30 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 22510, May 25, 1982]

§ 74.1331 D&C Red No. 31.

(a) *Identity.* (1) The color additive D&C Red No. 31 is principally the calcium salt of 3-hydroxy-4-(phenylazo)-2-naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 31 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 31 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.
Aniline, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, calcium salt, not more than 0.4 percent.
Subsidiary colors, not more than 1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Red No. 31 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 31 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1333 D&C Red No. 33.

(a) *Identity.* (1) The color additive D&C Red No. 33 is principally the disodium salt of 5-amino-4-hydroxy-3-(phenylazo)-2,7-naphthalenedisulfonic acid (CAS Reg. No. 3567-66-6). To manufacture the additive, the product obtained from the nitrous acid diazotization of aniline is coupled with 4-hydroxy-5-amino-2,7-naphthalenedisulfonic acid in an alkaline aqueous medium. The color additive is isolated as the sodium salt.

(2) Color additive mixtures for drug use made with D&C Red No. 33 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 33 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practices:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.
Water-insoluble matter, not more than 0.3 percent.

4-Amino-5-hydroxy-2,7-naphthalenedisulfonic acid, disodium salt, not more than 0.3 percent.
4,5-Dihydroxy-3-(phenylazo)-2,7-naphthalenedisulfonic acid, disodium salt, not more than 3.0 percent.
Aniline, not more than 25 parts per million.
4-Aminoazobenzene, not more than 100 parts per billion.
1,3-Diphenyltriazene, not more than 125 parts per billion.
4-Aminobiphenyl, not more than 275 parts per billion.
Azobenzene, not more than 1 part per million.
Benzidine, not more than 20 parts per billion.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 82 percent.

(c) *Uses and restrictions.* The color additive D&C Red. No 33 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 0.75 milligram per daily dose of the drug. D&C Red No. 33 may be safely used for coloring externally applied drugs, mouthwashes, and dentifrices in amounts consistent with current good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 33 shall be certified in accordance with regulations in Part 80 of this chapter.

[53 FR 33120, Aug. 30, 1988]

§ 74.1334 D&C Red No. 34.

(a) *Identity.* (1) The color additive D&C Red No. 34 is principally the calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azo]-2-naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 34 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 34 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated at sodium salts), not more than 15 percent.
2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.
Subsidiary colors, not more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color not less than 85 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 34 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1336 D&C Red No. 36.

(a) *Identity.* (1) The color additive D&C Red No. 36 is 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthalenol (CAS Reg. No. 2814-77-9). The color additive is manufactured by diazotization of 2-chloro-4-nitrobenzenamine in acid medium and coupling with 2-naphthalenol in acid medium.

(2) Color additive mixtures for drug use made with D&C Red No. 36 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* D&C Red No. 36 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter at 135 °C (275 °F), not more than 1.5 percent.

Matter insoluble in toluene, not more than 1.5 percent.

2-Chloro-4-nitrobenzenamine, not more than 0.3 percent.

2-Naphthalenol, not more than 1 percent.

2,4-Dinitrobenzenamine, not more than 0.02 percent.

1-[(2,4-Dinitrophenyl)azo]-2-naphthalenol, not more than 0.5 percent.

4-[(2-Chloro-4-nitrophenyl)azo]-1-naphthalenol, not more than 0.5 percent.

1-[(4-Nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.

1-[(4-Chloro-2-nitrophenyl)azo]-2-naphthalenol, not more than 0.3 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 95 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 36 may be safely used for coloring ingested drugs, other than mouthwashes and dentifrices, in amounts not to exceed 1.7 milligrams per daily dose of the drug for drugs that are taken continuously only for less than 1 year. For drugs taken continuously for longer than 1 year, the color additive shall not be used in amounts to exceed 1.0 milligram per daily dose of the drug. D&C Red No. 36 may be safely used for coloring externally applied drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 36 shall be certified in accordance with regulations in Part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988; 53 FR 35255, Sept. 12, 1988, as amended at 53 FR 52130, Dec. 27, 1988]

§ 74.1339 D&C Red No. 39.

(a) *Identity.* (1) The color additive D&C Red No. 39 is *o*-[*p*(β,β′-dihydroxy-diethylamino)-phenylazo]-benzoic acid.

(2) Color additive mixtures made with D&C Red No. 39 may contain the following diluents: Water, acetone, isopropyl alcohol, and specially denatured alcohols used in accordance with 26 CFR Part 212.

(b) *Specifications.* D&C Red No. 39 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 100° C.), not more than 2.0 percent.

Matter insoluble in acetone, not more than 1.0 percent.

Anthranilic acid, not more than 0.2 percent.

N,N-(β,β′-Dihydroxy-diethyl) aniline, not more than 0.2 percent.

Subsidiary colors, not more than 3.0 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 95.0 percent.

(c) *Uses and restrictions.* The color additive D&C Red No. 39 may be safely used for the coloring of quaternary ammonium type germicidal solutions intended for external application only, and subject to the further restriction that the quantity of the color additive does not exceed 0.1 percent by weight of the finished drug product.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Red No. 39 shall be certified in accordance with regulations promulgated under Part 80 of this chapter.

§ 74.1340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40

shall conform in identity and specifications to the requirements of § 74.340(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Red No. 40 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(3) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by §§ 82.51 or 82.1051 of this chapter.)

(b) *Uses and restrictions.* FD&C Red No. 40 may be safely used in coloring drugs, subject to the restrictions on use of color additives in § 70.5 of this chapter, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations, in Part 80 of this chapter.

§ 74.1602 D&C Violet No. 2.

(a) *Identity.* (1) The color additive D&C Violet No. 2 is principally 1-hydroxy -4-[(4-methylphenyl)amino]-9,10-anthracenedione.

(2) Color additive mixtures for use in externally applied drugs made with D&C Violet No. 2 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities can be avoided by good manufacturing practice:

Volatile matter (at 135° C.), not more than 2.0 percent.
Matter insoluble in both carbon tetrachloride and water, not more than 0.5 percent.
p-Toluidine, not more than 0.2 percent.
1-Hydroxy-9,10-anthracenedione, not more than 0.5 percent.
1,4-Dihydroxy-9,10-anthracenedione, not more than 0.5 percent.
Subsidiary colors, not more than 1.0 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 96.0 percent.

(c) *Uses and restrictions.* (1) The color additive D&C Violet No. 2 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(2) D&C Violet No. 2 may be safely used for coloring sutures for use in surgery subject to the following conditions:

(i) At a level not to exceed 0.2 percent by weight of the suture material for coloring polygalactin 910 (glycolic-lactic acid polyester) synthetic absorbable sutures for use in general and ophthalmic surgery;

(ii) At a level not to exceed 0.3 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for use in general and ophthalmic surgery; and

(iii) If the suture is a class III device, a premarket approval application under section 515 of the act is in effect for it.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

[42 FR 15654, Mar. 22, 1977, as amended at 45 FR 62978, Sept. 23, 1980]

§ 74.1705 FD&C Yellow No. 5.

(a) *Identity and specifications.* (1) The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705 (a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and are listed in Part 73 of

this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* FD&C Yellow No. 5 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) The label of OTC and prescription drug products intended for human use administered orally, nasally, rectally, or vaginally containing FD&C Yellow No. 5 shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive using the names FD&C Yellow No. 5 and tartrazine. The label shall bear a statement such as "Contains FD&C Yellow No. 5 (tartrazine) as a color additive" or "Contains color additives including FD&C Yellow No. 5 (tartrazine)." The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

(3) The labeling required by § 201.100(d) of this chapter for prescription drugs for human use containing FD&C Yellow No. 5 that are administered orally, nasally, vaginally, or rectally shall, in addition to the label statement required under paragraph (c)(2) of this section, bear the warning statement "This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity." This warning statement shall appear in the "Precautions" section of the labeling.

(d) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 501, 502, 701, 706(b), (c), and (d), 52 Stat. 1049-1051 as amended, 1055-1056 as amended, 74 Stat. 399-403 (21 U.S.C. 351, 352, 371, 376(b), (c), and (d)))

[42 FR 15654, Mar. 22, 1977, as amended at 44 FR 37220, June 26, 1979; 50 FR 35782, Sept. 4, 1985; 51 FR 24519, July 7, 1986]

§ 74.1706 FD&C Yellow No. 6.

(a) *Identity and specifications.* (1) The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Yellow No. 6 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* FD&C Yellow No. 6 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) [Reserved]

(d) *Certification.* All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986, as amended at 52 FR 21508, June 8, 1987; 53 FR 49138, Dec. 6, 1988]

EFFECTIVE DATE NOTE: At 53 FR 49138, Dec. 6, 1988, § 74.1706(c)(2) was suspended, effective December 6, 1988. For the convenience of the user, the suspended text follows.

§ 74.1706 FD&C Yellow No. 6.

* * * * *

(c) * * *

(2) The label of over-the-counter drug products intended for human use administered orally, nasally, rectally, or vaginally containing FD&C Yellow No. 6 shall specifically declare the presence of FD&C Yellow No. 6 by listing the color additive using the name FD&C Yellow No. 6. The labeling for over-the-counter and prescription drug products containing FD&C Yellow No. 6 shall declare the presence of FD&C Yellow No. 6. The labels for certain drug products subject to this labeling requirement that are

also cosmetics, such as antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

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§ 74.1707 D&C Yellow No. 7.

(a) *Identity.* (1) The color additive D&C Yellow No. 7 is principally fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 6 percent.

Matter insoluble in alkaline water, not more than 0.5 percent.

Resorcinol, not more than 0.5 percent.

Phthalic acid, not more than 0.5 percent.

2-2,4-(Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 94 percent.

(c) *Uses and restrictions.* D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1707a Ext. D&C Yellow No. 7.

(a) *Identity.* (1) The color additive Ext. D&C Yellow No. 7 is principally the disodium salt of 8-hydroxy-5,7-dinitro-2-naphthalenesulfonic acid.

(2) Color additive mixtures for drug use made with Ext. D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Ext. D&C Yellow No. 7 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water-insoluble matter, not more than 0.2 percent.

1-Naphthol, not more than 0.2 percent.

2,4-Dinitro-1-naphthol, not more than 0.03 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 85 percent.

(c) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1708 D&C Yellow No. 8.

(a) *Identity.* (1) The color additive D&C Yellow No. 8 is principally the disodium salt of fluorescein.

(2) Color additive mixtures for use in externally applied drugs made with D&C Yellow No. 8 may contain only those diluents that are suitable and that are listed in Part 73 of this chap-

ter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 8 shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Sum of water and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Matter insoluble in alkaline water, not more than 0.3 percent.
Resorcinol, not more than 0.5 percent.
Phthalic acid, not more than 1 percent.
2-(2,4-Dihydroxybenzoyl) benzoic acid, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* D&C Yellow No. 8 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.1710 D&C Yellow No. 10.

(a) *Identity.* (1) The color additive D&C Yellow No. 10 is a mixture of the sodium salts of the mono- and disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione consisting principally of the sodium salts of 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-6-quinolinesulfonic acid and 2-(2,3-dihydro-1,3-dioxo-1*H*-indene-2-yl)-8-quinolinesulfonic acid with lesser amounts of the disodium salts of the disulfonic acids of 2-(2-quinolinyl)-1*H*-indene-1,3(2*H*)-dione (CAS Reg. No. 8004-92-0). D&C Yellow No. 10 is manufactured by condensing quinaldine with phthalic anhydride to give the unsulfonated dye, which is then sulfonated with oleum.

(2) Color additive mixtures made with D&C Yellow No. 10 for drug use may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* The color additive D&C Yellow No. 10 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135° C (275° F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Matter insoluble in both water and chloroform, not more than 0.2 percent.
Total sulfonated quinaldines, sodium salts, not more than 0.2 percent.
Total sulfonated phthalic acids, sodium salts, not more than 0.2 percent.
2-(2-Quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 4 parts per million.
Sum of sodium salts of the monosulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not less than 75 percent.
Sum of sodium salts of the disulfonates of 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione, not more than 15 percent.
2-(2,3-Dihydro-1,3-dioxo-1*H*-indene-2-yl)-6, 8-quinolinedisulfonic acid, disodium salt, not more than 3 percent.
Diethyl ether soluble matter other than that specified, not more than 2 parts per million, using added 2-(2-quinolinyl)-1*H*-indene-1,3 (2*H*)-dione for calibration.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in Part 80 of this chapter.

(Sec. 706(b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376(b), (c), and (d); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note); secs. 701, 706(b), (c), and (d), 52 Stat. 1055-1056 as amended, 74 Stat. 399-403 as amended (21 U.S.C. 371, 376 (b), (c), and (d); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note))

[48 FR 39219, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.1711 D&C Yellow No. 11.

(a) *Identity.* (1) The color additive D&C Yellow No. 11 is principally 2-(2-quinolyl)-1,3-indandione.

(2) Color additive mixtures, for drug use made with D&C Yellow No. 11 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Yellow No. 11 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter (at 135° C), not more than 1 percent.
Ethyl alcohol-insoluble matter, not more than 0.4 percent.
Phthalic acid, not more than 0.3 percent.
Quinaldine, not more than 0.2 percent.
Subsidiary colors, not more than 5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 96 percent.

(c) *Uses and restrictions.* D&C Yellow No. 11 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

Subpart C—Cosmetics

§ 74.2101 FD&C Blue No. 1.

(a) *Identity.* The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl[4-[*p*-[ethyl(*m*-sulfobenzyl)amino]-*α*-(*o*-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene](*m*-sulfobenzyl)ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl[4-[*p*-[ethyl(*p*-sulfobenzyl)amino]-*α*-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*p*-sulfobenzyl)ammonium hydroxide inner salt and ethyl[4-[*p*-[ethyl(*o*-sulfobenzyl)amino]-*α*-(*o*-sulfophenyl)benzylidene]-2,5-cyclohexadien-1-ylidene](*o*-sulfobenzyl)ammonium hydroxide inner salt. Additionally, FD&C Blue No. 1 is manufactured by the acid catalyzed condensation of one molecule of sodium 2-formylbenzene-sulfonate with two molecules from a mixture consisting principally of 3-[(ethylphenylamino)methyl]benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl]benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid, or with dichromate and acid to form the dye. The intermediate sodium 2-formylbenzenesulfonate is prepared from 2-chlorobenzaldehyde and sodium sulfite.

(b) *Specifications.* The color additive FD&C Blue No. 1 shall conform in specifications to the requirements of § 74.101(b).

(c) *Uses and restrictions.* FD&C Blue No. 1 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub

L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 42565, Sept. 28, 1982]

§ 74.2104 D&C Blue No. 4.

(a) *Identity and specifications.* The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b).

(b) *Uses and restrictions.* D&C Blue No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Blue No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2151 D&C Brown No. 1.

(a) *Identity.* The color additive D&C Brown No. 1 is a mixture of the sodium salts of 4[[5-[(dialkylphenyl)-azo]-2,4-dihydroxyphenyl]azo]-benzene sulfonic acid. The alkyl group is principally the methyl group.

(b) *Specifications.* D&C Brown No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 16 percent.
Water-insoluble matter, not more than 0.2 percent.
Sulfanilic acid, sodium salt, not more than 0.2 percent.
Resorcinol, not more than 0.2 percent.
Xylidines, not more than 0.2 percent.
Disodium salt of 4[[5-[(4-sulfophenyl)-azo]-2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not more than 3 percent.
Monosodium salt of 4[[5-[(2,4-dimethylphenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 29 percent and not more than 39 percent.
Monosodium salt of 4[[5-[(2,5-dimethylphenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 12 percent and not more than 17 percent.
Monosodium salt of 4[[5-[(2,3-dimethylphenyl)azo] - 2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 6 percent and not more than 13 percent.
Monosodium salt of 4[[5-[(2-ethylphenyl)azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 5 percent and not more than 12 percent.
Monosodium salt of 4[[5-[(3,4-dimethylphenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 9 percent.
Monosodium salt of 4[[5-[(2,6-dimethylphenyl)azo] -2,4-dihydroxyphenyl]azo] benzenesulfonic acid, not less than 3 percent and not more than 8 percent.
Monosodium salt of 4[[5-[(4-ethylphenyl)azo]-2,4-dihydroxyphenyl]-azo] benzenesulfonic acid, not less than 2 percent and not more than 8 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 84 percent.

(c) *Uses and restrictions.* D&C Brown No. 1 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Brown No. 1 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2203 FD&C Green No. 3.

(a) *Identity and specifications.* The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b).

(b) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 52144, Nov. 19, 1982]

§ 74.2205 D&C Green No. 5.

(a) *Identity and specifications.* The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205 (a)(1) and (b)(2).

(b) *Uses and restrictions.* D&C Green No. 5 may be safely used for color cosmetics generally except in the area of the eye in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Green No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 24285, June 4, 1982]

§ 74.2206 D&C Green No. 6.

(a) *Identity and specifications.* The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b).

(b) *Uses and restrictions.* D&C Green No. 6 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 14146, Apr. 4, 1982, as amended at 21 FR 9784, Mar. 21, 1986]

§ 74.2208 D&C Green No. 8.

(a) *Identity and specifications.* The color additive D&C Green No. 8 shall conform in identity and specifications to the requirements of § 74.1208(a)(1) and (b).

(b) *Uses and restrictions.* D&C Green No. 8 may be safely used for coloring externally applied cosmetics in amounts not exceeding 0.01 percent by weight of the finished cosmetic product.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Green No. 8 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2254 D&C Orange No. 4.

(a) *Identity and specifications.* The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

[42 FR 52396, Sept. 30, 1977]

§ 74.2255 D&C Orange No. 5.

(a) *Identity and specifications.* The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 5 may be safely used for coloring mouthwashes and dentifrices that are ingested cosmetics in amounts consistent with current good manufacturing practice. D&C Orange No. 5 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 5.0 percent by weight of the finished cosmetic products. D&C Orange No. 5 may be safely used for coloring externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 5 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 49635, Nov. 2, 1982, as amended at 49 FR 13342, Apr. 4, 1984]

§ 74.2260 D&C Orange No. 10.

(a) *Identity and specifications.* The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements of § 74.1260(a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 10 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

[46 FR 18954, Mar. 27, 1981]

§ 74.2261 D&C Orange No. 11.

(a) *Identity and specifications.* The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

[46 FR 18954, Mar. 27, 1981]

§ 74.2304 FD&C Red No. 4.

(a) *Identity and specifications.* The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of § 74.1304(a)(1) and (b).

(b) *Uses and restrictions.* FD&C Red No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2306 D&C Red No. 6.

(a) *Identity and specifications.* The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of § 74.1306 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 6 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 57688, Dec. 28, 1982]

§ 74.2307 D&C Red No. 7

(a) *Identity and specifications.* The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of § 74.1307 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 7 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 57688, Dec. 28, 1982]

§ 74.2317 D&C Red No. 17.

(a) *Identity and specifications.* The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 17 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 17 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2321 D&C Red No. 21.

(a) *Identity and specifications.* The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 21 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 21 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 53846, Nov. 30, 1982]

§ 74.2322 D&C Red No. 22.

(a) *Identity and specifications.* The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 22 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 22 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 53846, Nov. 30, 1982]

§ 74.2327 D&C Red No. 27.

(a) *Identity and specifications.* The color additive D&C Red No. 27 shall conform in identity and specifications to the requirements of § 74.1327 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 27 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 27 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 42568, Sept. 28, 1982]

§ 74.2328 D&C Red No. 28.

(a) *Identity and specifications.* The color additive D&C Red No. 28 shall conform in identity and specifications to the requirements of § 74.1328 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 28 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 28 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 42568, Sept. 28, 1982]

§ 74.2330 D&C Red No. 30.

(a) *Identity and specifications.* The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 30 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 30 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 22511, May 25, 1982]

§ 74.2331 D&C Red No. 31.

(a) *Identity and specifications.* The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 31 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 31 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2333 D&C Red No. 33.

(a) *Identity and specifications.* The color additive D&C Red No. 33 shall conform in identity and specifications to the requirements of § 74.1333(a) (1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 33 may be safely used for coloring cosmetic lip products in amounts not to exceed 3 percent total color by weight of the finished cosmetic products. D&C Red No. 33 may be safely used for coloring mouthwashes (including breath fresheners), dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 33 shall be certified in accordance with regulations in Part 80 of this chapter.

[53 FR 33120, Aug. 30, 1988]

§ 74.2334 D&C Red No. 34.

(a) *Identity and specifications.* The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 74.1334(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 34 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2336 D&C Red No. 36.

(a) *Identity and specifications.* The color additive D&C Red No. 36 shall conform in identity and specifications to the requirements of § 74.1336 (a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Red No. 36 may be safely used for coloring cosmetic lip products in amounts not to exceed 3 percent total color by weight of the finished cosmetic products. D&C Red

No. 36 may be safely used for coloring externally applied cosmetics in amounts consistent with current good manufacturing practice.

(c) *Labeling requirements.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Red No. 36 shall be certified in accordance with regulations in Part 80 of this chapter.

[53 FR 29031, Aug. 2, 1988]

§ 74.2340 FD&C Red No. 40.

(a) *Identity and specifications.* (1) The color additive FD&C Red No. 40 shall conform in identity and specifications to the requirements of § 74.340(a)(1) and (b) of this chapter.

(2) The listing of this color additive includes lakes prepared as described in §§ 82.51 and 82.1051 of this chapter, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by § 82.51 or § 82.1051 of this chapter.

(b) *Uses and restrictions.* FD&C Red No. 40 may be safely used in coloring cosmetics generally subject to the following restrictions:

(1) The color additive may be used in amounts consistent with good manufacturing practice.

(2) The color additive shall not be exposed to oxidizing or reducing agents which may affect the integrity of the color or any other conditions which may affect the integrity of the color.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Red No. 40 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2602 D&C Violet No. 2.

(a) *Identity and specifications.* The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2602a Ext. D&C Violet No. 2.

(a) *Identity.* The color additive Ext. D&C Violet No. 2 is principally the monosodium salt of 2-[(9,10-dihydro-4-hydroxy -9,10-dioxo-1-anthracenyl) amino]-5-methyl-benzenesulfonic acid.

(b) *Specifications.* Ext. D&C Violet No. 2 shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 18 percent.
Water-insoluble matter, not more than 0.4 percent.
1-Hydroxy-9,10-anthracenedione, not more than 0.2 percent.
1,4-Dihydroxy-9,10-anthracenedione, not more than 0.2 percent.
p-Toluidine, not more than 0.1 percent.
p-Toluidine sulfonic acids, sodium salts, not more than 0.2 percent.
Subsidiary colors, not more than 1 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 80 percent.

(c) *Uses and restrictions.* The color additive Ext. D&C Violet No. 2 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of Ext. D&C Violet No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2705 FD&C Yellow No. 5.

(a) *Identity.* The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-(1-

4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid (CAS Reg. No. 1934-21-0). To manufacture the additive, 4-aminobenzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt.

(b) *Specifications.* FD&C Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.
Water-insoluble matter, not more than 0.2 percent.
4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1 percent.
4-[(4',5-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1 percent.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazole-3-carboxylate, disodium salt, not more than 1 percent.
Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1*H*-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.
4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.
4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.
4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.
4-Aminoazobenzene, not more than 75 parts per billion.
4-Aminobiphenyl, not more than 5 parts per billion.
Aniline, not more than 100 parts per billion.
Azobenzene, not more than 40 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87 percent.

(c) *Uses and restrictions.* FD&C Yellow No. 5 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in Part 80 of this chapter

[50 FR 35782, Sept. 4, 1985, as amended at 51 FR 24524, July 7, 1986]

§ 74.2706 FD&C Yellow No. 6.

(a) *Identity and specifications.* The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706 (a)(1) and (b).

(b) *Uses and restrictions.* FD&C Yellow No. 6 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

[51 FR 41782, Nov. 19, 1986]

§ 74.2707 D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2707a Ext. D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707a (a)(1) and (b).

(b) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2708 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 8 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in Part 80 of this chapter.

§ 74.2710 D&C Yellow No. 10.

(a) *Identity and specifications.* The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b).

(b) *Uses and restrictions.* The color additive D&C Yellow No. 10 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in Part 80 of this chapter.

(Sec. 706(b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376(b), (c), and (d); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note); secs. 701, 706(b), (c), and (d), 52 Stat. 1055-1056 as amended, 74 Stat. 399-403 as amended (21 U.S.C. 371, 376 (b), (c), and (d); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note))

[48 FR 39220, Aug. 30, 1983, as amended at 49 FR 8432, Mar. 7, 1984]

§ 74.2711 D&C Yellow No. 11.

(a) *Identity and specifications.* The color additive D&C Yellow No. 11 shall conform in identity and specifications to the requirements of § 74.1711(a)(1) and (b).

(b) *Uses and restrictions.* D&C Yellow No. 11 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 11 shall be certified in accordance with regulations in Part 80 of this chapter.

Subpart D—Medical Devices

§ 74.3045 [Phthalocyaninato(2-)] copper.

(a) *Identity.* The color additive is [phthalocyaninato(2-)] copper (CAS Reg. No. 147-14-8) having the structure shown in Colour Index No. 74160.

(b) *Specifications.* The color additive [phthalocyaninato(2-)] copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Volatile matter 135° C (275° F), not more than 0.3 percent.
Salt content (as NaCl), not more than 0.3 percent.
Alcohol soluble matter, not more than 0.5 percent.
Organic chlorine, not more than 0.5 percent.
Aromatic amines, not more than 0.05 percent.
Lead (as Pb), not more than 40 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 98.5 percent.

(c) *Uses and restrictions.* (1) The color additive [phthalocyaninato (2-)] copper may be safely used to color polypropylene sutures, polybutester (the generic designation for the suture fabricated from 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol and *alpha*-hydro-*omega*- hydroxypoly (oxy-1,4-butanediyl), CAS Reg. No. 37282-12-5) nonabsorbable sutures for use in general and ophthalmic surgery, and polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses, subject to the following restrictions:

(i) The quantity of the color additive does not exceed 0.5 percent by weight of the suture or haptic material.

(ii) The dyed suture shall conform in all respects to the requirements of the U.S. Pharmacopeia.

(2) The color additive [phthalocyaninato(2-)] copper may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(3) Authorization for these uses shall not be construed as waiving any of the requirements of section 510(k), 515, or 520(g) the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which [phthalocyaninato(2-)] copper is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of [phthalocyaninato (2-)] copper shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[48 FR 34947, Aug. 2, 1983, as amended at 50 FR 16228, Apr. 25, 1985; 51 FR 22929, June 24, 1986; 51 FR 28930, Aug. 13, 1986; 51 FR 39371, Oct. 28, 1986; 52 FR 15945, May 1, 1987]

§ 74.3106 D&C Blue No. 6.

(a) *Identity.* The color additive D&C Blue No. 6 is principally [$\Delta^{2,2'}$-biindoline]-3,3' dione (CAS Reg. No. 482-89-3).

(b) *Specifications.* D&C Blue No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Volatile matter at 135 °C (275 °F), not more than 3 percent.

Matter insoluble in *N,N*-dimethylformamide, not more than 1 percent.

Isatin, not more than 0.3 percent.

Anthranilic acid, not more than 0.3 percent.

Indirubin, not more than 1 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 95 percent.

(c) *Uses and restrictions.* (1) D&C Blue No. 6 may be safely used at a level—

(i) Not to exceed 0.2 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures for general surgical use;

(ii) Not to exceed 0.25 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for general surgical use;

(iii) Not to exceed 0.5 percent by weight of the suture material for coloring plain or chromic collagen absorbable sutures for ophthalmic surgical use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polypropylene surgical sutures for general surgical use; and

(v) Not to exceed 0.5 percent by weight of the suture material for coloring polydioxanone synthetic absorbable sutures for ophthalmic and general surgical use.

(2) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which the color additive is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Blue No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371(e), 376))

[49 FR 29956, July 25, 1984; 49 FR 34447, Aug. 31, 1984, as amended at 50 FR 30698, July 29, 1985]

§ 74.3206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 shall conform in identity to the requirements of § 74.1206(a).

(b) *Specifications.* The color additive D&C Green No. 6 for use in medical devices shall conform to the specifications of § 74.1206(b).

(c) *Uses and restrictions.* (1) The color additive D&C Green No. 6 may be safely used at a level

(i) Not to exceed 0.03 percent by weight of the lens material for coloring contact lenses;

(ii) Not to exceed 0.75 percent by weight of the suture material for coloring polyethylene terephthalate surgical sutures, including sutures for ophthalmic use;

(iii) Not to exceed 0.1 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter greater than U.S.P. size 8-0, including sutures for ophthalmic use;

(iv) Not to exceed 0.5 percent by weight of the suture material for coloring polyglycolic acid surgical sutures with diameter not greater than U.S.P. size 8-0, including sutures for ophthalmic use; and

(v) Not to exceed 0.21 percent by weight of the suture material for coloring poly(glycolic acid-co-trimethylene carbonate) sutures (also referred to as 1,4-dioxan-2,5-dione polymer with 1,3-dioxan-2-one) for general surgical use.

(2) Authorization for these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which D&C Green No. 6 is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

[48 FR 13022, Mar. 29, 1983, as amended at 51 FR 9784, Mar. 21, 1986; 51 FR 37909, Oct. 27, 1986]

§ 74.3602 D&C Violet No. 2.

(a) *Identity and specifications.* The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b).

(b) *Uses and restrictions.* (1) The color additive, D&C Violet No. 2, may be safely used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of section 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Violet No. 2 shall be certified in accordance with regulations in Part 80 of this chapter.

[52 FR 19722, May 27, 1987]

§ 74.3710 D&C Yellow No. 10.

(a) *Identity.* The color additive D&C Yellow No. 10 shall conform to the identity requirements of § 74.1710(a).

(b) *Specifications.* The color additive D&C Yellow No. 10 for use in contact lenses shall conform to the specifications of § 74.1710(b).

(c) *Uses and restrictions.* (1) The color additive D&C Yellow No. 10 may be used for coloring contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the

contact lens in which the color additive is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Yellow No. 10 shall be certified in accordance with regulations in Part 80 of this chapter.

[52 FR 28690, Aug. 3, 1987]

APPENDIX A TO PART 74—THE PROCEDURE FOR DETERMINING ETHER SOLUBLE MATERIAL IN D&C RED NOS. 6 AND 7

The dye is dissolved in glacial acetic and 8 *N* hydrochloric acids (1.33 : 1) and extracted with diethyl ether. Sulfonated moieties, including the color additive, are discarded in subsequent aqueous extractions of the ether. Carboxylated moieties are removed from the ether by extraction with 2% (w/w) NaOH. The ether is evaporated to near dryness, ethanol (95%) is added, and the solution is analyzed spectrophotometrically in the visible range. The absorbance at each wavelength must not exceed 150% of the absorbance similarly obtained for D&C Red No. 6 Lot AA5169.

APPARATUS

(A) Spectrophotometer (Cary 118 or equivalent).

(B) Separatory funnels—one 1000 mL and one 500 mL.

REAGENTS

NOTE: Use *distilled* water when water is required.

(A) Glacial Acetic Acid (ACS grade).

(B) Diethyl ether (Anhydrous)—Note and follow safety precautions on container.

(C) 8 *N* HCl—Pour 165 mL H_2O into a 500 mL graduate. Place the graduate in hood, then add HCl conc. to bring to volume. Carefully pour this solution into a 500 mL Erlenmeyer flask. Stopper and shake. Label the flask.

(D) 2% (w/w) NaOH—Pour ca 190 mL H_2O into a 250 mL mixing graduate. Add 8 g. (5.23 mL) of 50% (w/w) NaOH, bring to 200 mL volume with water, stopper and mix. Pour this solution into a glass bottle, label and stopper with a polytetrafluoroethylene top.

(E) Ethanol (95%).

PROCEDURE

Weigh a 250 mL beaker to tenths of a mg and add 100 mg of dye. Record weight to tenths of a mg.

NOTE: The following work must be performed in the hood.

Add 75 mL of 8 *N* HCl and 100 mL of glacial acetic acid to the beaker and stir.

Place the beaker on a hot plate and heat with stirring, until all of the dye is in solution.

Remove the beaker from the hot plate, cover with a watch glass and allow to cool to room temperature (1–2 hrs).

When the dye solution is at room temperature, transfer the solution to a 1000 mL separatory funnel.

Rinse the beaker three times with 50 mL portions of H_2O, transferring each rinse to the 1000 mL funnel.

Add 150 mL of ether to the funnel, stopper and shake for 10 seconds, then invert funnel and open stopcock to remove gas buildup.

Shake the funnel for one minute, opening the stopcock a few times while the funnel is inverted to remove gas buildup. (Use this shake procedure throughout method.)

Allow the funnel to stand until the layers have separated.

Transfer the bottom (aqueous) layer to a 500 mL separatory funnel, add 100 mL of ether, stopper and shake for one minute.

When the layers have separated, drain off the bottom layer into a waste beaker.

Pour the ether layer in the 500 mL separatory funnel into the 1000 mL separatory funnel.

Rinse the 500 mL sep. funnel with 100 mL H_2O, then transfer it to the 1000 mL sep. funnel, stopper and shake for one minute.

When the layers have separated, drain off the bottom aqueous layer into the waste beaker.

Rinse the 500 mL funnel at least three times (total) and repeat the 100 mL water washes until no color is present in the aqueous layer. Discard the bottom aqueous layer to the waste beaker after each separation.

Shake the ether layer twice more with 100 mL portions of H_2O, discarding the bottom aqueous layer after each separation.

Remove the unsulfonated subsidiary color from the ether by shaking the ether layer for one minute with 20 mL of 2% (w/w) NaOH. *Appropriately label* a 100 mL beaker. After the layers separate, drain the aqueous alkaline layer into the beaker and save for the determination of 3-hydroxy-4-[(4-methylphenyl) azo]-2-naphthalenecarboxylic acid, sodium salt.

If there is any color left in the ether, shake for one minute with another 20 mL portion of 2% (w/w) NaOH. After the layers have separated, drain off the aqueous alkaline layer into the 100 mL beaker.

If color remains in the ether layer, repeat the above step for a total of three washes of the ether with 2% (w/w) NaOH. Note:

Three washes is usually sufficient to remove the unsulfonated subsidiary.

With the stopper removed, *gently* swirl the ether layer in the sep. funnel twice to separate the remaining aqueous base. Drain this into the 100 mL beaker.

Appropriately label a 250 mL beaker. *Pour* the ether layer into the beaker. Allow the ether to evaporate to *near* dryness. Cool to room temperature. Add ca 8 mL ethanol (95%). Swirl beaker to mix contents. Quantitatively transfer to a 25 mL graduate using ethanol (95%) rinses. Add ethanol (95%) to bring volume to 15 mL.

Spectrophotometric Analysis

Spectrophotometer Parameters:

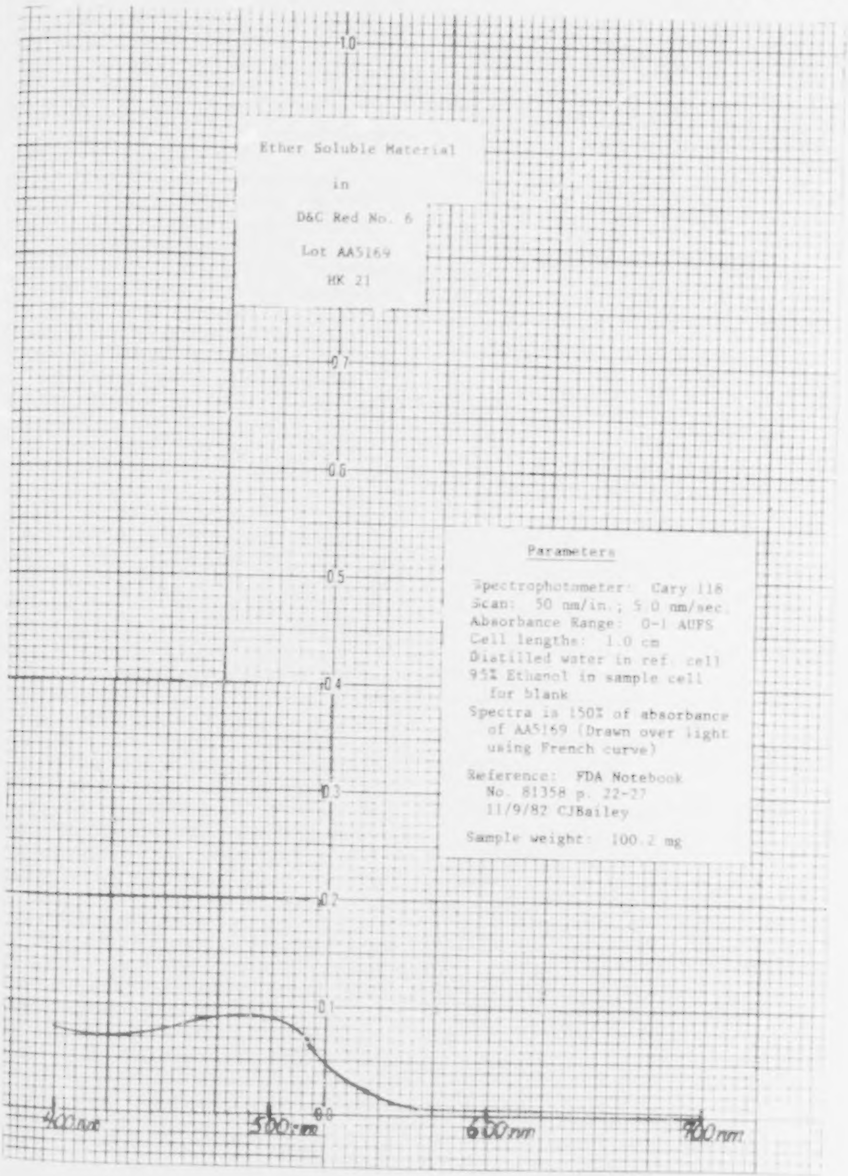
Scan Range: 400-700 nm
Scan: 50 nm/in; 5.0 nm/sec.
Absorbance Range: 0-1 AUFS
Cell length: 1 cm (Note: Reference and Sample cells)

(1) Record the visible spectrum of a blank. Fill the reference cell with distilled water and the sample cell with ethanol (95%).

(2) Rinse the sample cell with 2-3 mL of the ether soluble material (in ethanol solution); then fill the cell. Record the visible spectrum of the ether soluble material.

(3) Compare the spectra obtained to the spectra attached. The attached spectra represents 150% of the absorbance at each wavelength for similarly analyzed D&C Red No. 6 Lot AA5169.

The spectra of the current sample must not exceed the attached spectra at any wavelength in order to *pass test*.



Ether Soluble Material

in

D&C Red No. 6

Lot AA5169

HK 21

Parameters

Spectrophotometer: Cary 118
Scan: 50 nm/in.; 5.0 nm/sec.
Absorbance Range: 0-1 AUFS
Cell lengths: 1.0 cm
Distilled water in ref. cell
95% Ethanol in sample cell
for blank
Spectra is 150% of absorbance
of AA5169 (Drawn over light
using French curve)

Reference: FDA Notebook
No. 81358 p. 22-27
11/9/82 CJBailey

Sample weight: 100.2 mg

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 57688, Dec. 28, 1982; 48 FR 3946, Jan. 28, 1983; 48 FR 7438, Feb. 22, 1983; 48 FR 10811, Mar. 15, 1983]

PART 80—COLOR ADDITIVE CERTIFICATION

Subpart A—General Provisions

Sec.
80.10 Fees for certification services.

Subpart B—Certification Procedures

80.21 Request for certification.
80.22 Samples to accompany requests for certification.
80.31 Certification.
80.32 Limitations of certificates.
80.34 Authority to refuse certification service.
80.35 Color additive mixtures; certification and exemption from certification.
80.37 Treatment of batch pending certification.
80.38 Treatment of batch after certification.
80.39 Records of distribution.

AUTHORITY: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376).

SOURCE: 42 FR 15662, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 80.10 Fees for certification services.

(a) *Fees for straight colors including lakes.* The fee for the services provided by the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(1) and (2) shall be 25 cents per pound of the batch covered by such requests, but no such fee shall be less than $160.00.

(b) *Fees for repacks of certified color additives and color additives mixtures.* The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 80.21(j)(3) and (4) shall be:

(1) *Fees for straight colors including lakes.* 25 cents per pound of the batch covered but not less than $160.

(2) *Repacks of certified color, color additives, and color additive mixtures.* (i) 100 pounds or less—$25.

(ii) Over 100 pounds but not over 1,000 pounds—$25 plus 6 cents for each pound over 100 pounds.

(iii) Over 1,000 pounds—$79 plus 2 cents per pound for each pound in excess of 1,000 pounds.

(c) *Advance deposits.* Any person regularly requesting certification services may deposit funds in advance of requests as prepayment of fees required by this section.

(d) *Method of payment.* All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Food and Drug Administration, collectable at par at Washington, D.C. All such deposits and fees shall be forwarded to the Division of Color Technology, HFF-430, Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, whereupon after making appropriate records thereof, they will be transmitted to the Treasurer of the United States for deposit to the special account "Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration."

(e) *Refunds from advance deposits.* Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than $5.00.

(Sec. 706(c) and (e), 74 Stat. 402-403 (21 U.S.C. 376(c) and (e))

[42 FR 15662, Mar. 22, 1977, as amended at 47 FR 24692, June 8, 1982]

Subpart B—Certification Procedures

§ 80.21 Request for certification.

A request for certification of a batch of color additive shall:

(a) Be addressed to the Commissioner of Food and Drugs.

(b) Be prepared in the manner set forth in paragraph (j) of this section.

(c) Be submitted in duplicate.

(d) Be signed by a responsible officer of the person requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.

(e) Show the name and post office address of the actual manufacturer in case such manufacturer is not the person requesting certification of the batch.

(f) Be accompanied by the fee prescribed in § 80.10 unless the person has established with the Food and Drug Administration an advanced deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a request for certification of a batch of color additive if the fee accompanying such request is less than that required by § 80.10 or if such fee exceeds the amount held in the advance deposit account of the manufacturer submitting such request for certification.

(g) Be accompanied by the sample prescribed in § 80.22 consisting of:

(1) Four ounces in the case of straight colors and lakes.

(2) Two ounces in the case of repacks and mixtures.

A sample accompanying a request for certification must be submitted under separate cover and should be addressed to the Color Certification Branch.

(h) The name of a color additive shall be given in the following manner:

(1) The name of a straight color shall be the name of the color as listed in Parts 74 and 81 of this chapter.

(2) The name of a lake shall be the name derived in the manner described in Part 82 of this chapter.

(3) The name of a mixture shall be the name given to such mixture by the person requesting certification.

(4) The name of a repack shall be the name described in paragraph (h)(1), (2), or (3) of this section, whichever is applicable.

(i) The information and samples enumerated in paragraphs (a) to (h), inclusive, of this section are the minimum required. Additional information and samples shall be submitted at the request of the Food and Drug Administration when such additional information and samples are necessary to determine compliance with the requirements of § 80.31 for the issuance of a certificate.

(j) The form for submission of the application shall be one of the following, depending upon whether the color additive is a straight color, a lake, a repack of a previously certified color additive, or a color additive mixture.

(1) *Request for certification of a batch of straight color additive.*

Date ————————

Division of Color Technology,
HFF-430, Bureau of Foods,
Food and Drug Administration,
200 C St., SW.,
Washington, D.C. 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of straight color additive.

Name of color ————————
(As listed in 21 CFR Part 74)

Batch number ————————
(Manufacturer's number)

Batch weighs ———————— pounds

Batch manufactured by ————————

at ————————(Name and address of actual manufacturer)

How stored pending certification ————————

————————

(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested of this color for use in ————————

————————

————————

(State proposed uses)

Required fee, $———— (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21

CFR 80.22 and is accurately representative thereof.

(Signed) __________
By __________
____
(Title)

(2) *Request for certification of a batch of color additive lake.*

Date __________

Division of Color Technology,
HFF-430, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive lake.

Name of color __________
Batch number __________
(Manufacturer's number)
Batch weighs __________ pounds
Name of color used __________
Quantity __________ pounds
Lot number __________
(When certification of the lake for use in foods is requested)
Precipitant used __________
Substratum used __________
Quantity __________ pounds
Batch manufactured by __________
at __________ (Name and address of actual manufacturer)
How stored pending certification __________
____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested of this color for use in __________
____
____
(State proposed uses)

Required fee, $____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) __________
By __________
____
(Title)

(3) *Request for certification of a repack of a batch of certified color additive.*

Date __________

Division of Color Technology,
HFF-430, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive repack.

Name of color __________
(As listed in regulations and as certified; or repacker's name, if a mixture)
Original lot number __________
Certified color content __________
This color obtained from __________
Batch number __________
Batch weighs __________ pounds
How stored pending certification __________
____
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested for use in __________
____
____
(State proposed uses)

Required fee, $____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) __________
By __________
____
(Title)

(4) *Request for certification of a batch of color additive mixture.*

Date __________

Division of Color Technology,
HFF-430, Bureau of Foods,
Food and Drug Administration,
200 C St. SW.,
Washington, D.C. 20204

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive mixture.

Name of mixture __________
(Manufacturer's trade name)
Batch number __________
(Manufacturer's number)
Weight of batch __________ pounds
Volume of batch __________ (If liquid) gallons
Batch manufactured by __________
Constituents of the mixture:
1. Color(s). (List separately each color and each lot number.)

Name of color as certified	Lot number

Quantity used (in pounds)	*Obtained from*

2. List of diluents. (List separately each diluent.)

Name of diluent

Quantity used	
By weight	By volume (*if liquid*)

Batch mixed as follows ________________
(Describe in detail)

How stored pending certification ________________
____
(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested for use in ________________
____
____
(State proposed uses)

Required fee, $——— (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) ________________
By ________________
____
(Title)

[42 FR 15662, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979; 44 FR 22053, Apr. 13, 1979]

§ 80.22 Samples to accompany requests for certification.

A sample of a batch of color additive which is to accompany a request for certification shall:

(a) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout.

(b) Held under the control of the person requesting certification until certified.

(c) Be labeled to show:

(1) The name of the color additive.

(2) The manufacturer's batch number.

(3) The quantity of such batch.

(4) The name and post-office address of the person requesting certification of such batch.

(5) Be accompanied by any label or labeling intended to be used.

§ 80.31 Certification.

(a) If the Commissioner determines, after such investigations as he considers to be necessary, that:

(1) A request submitted in accordance with § 80.21 appears to contain no untrue statement of a material fact;

(2) Such color additive conforms to the specifications and any other conditions set forth therefor in Parts 81 and 82 of this chapter.

(3) The batch covered by such request otherwise appears to comply with the regulations in this chapter, the Commissioner shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by Part 74, 81, and 82 of this chapter, is a certified batch.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that a request submitted in accordance with § 80.21, or the batch of color additive covered by such request, does not comply with the requirements prescribed by paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating his reasons for refusal. Any person who contests such refusal shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

§ 80.32 Limitations of certificates.

(a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and a color additive from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with the regulations in this part. Whenever, the Commissioner learns that any certificate has been obtained through fraud or material misrepresentation, he shall notify the holder of the certificate that it is of no effect.

(b) If between the time a sample of color additive accompanying a request for certification is taken and the time a certificate covering the batch of such color additive is received by the person to whom it is issued, any such color additive becomes changed in composition, such certificates shall not be effective with respect to such changed color additive and such changed color additive shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

(c) If at any time after a certificate is received by the person to whom it is issued any color additive from the batch covered by such certificate becomes changed in composition, such certificate shall expire with respect to such changed color additive. After such expiration, such color additive shall be considered to be from a batch that has not been certified in accordance with this part; except that such color additive shall not be so considered when used for coloring a food, drug, or cosmetic, or for the purpose of certifying a batch of a mixture in which such color additive was used as an ingredient, or for use in preparing a batch of a mixture for which exemption from certification has been authorized, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any color additive covered thereby if the package in which such color additive was closed for shipment or delivery is opened. After such expiration such color additive shall be considered to be from a batch that has not been certified, except that such color additive shall not be so considered when the package is opened;

(1) and such color additive is used, subject to the restrictions prescribed by paragraphs (f), (g), and (h) of this section, in coloring a food, drug, or cosmetic;

(2) for the purpose of certifying a batch made by repacking such color;

(3) for the purpose of certifying a batch of a mixture in which such color is used as an ingredient; or

(4) for the purpose of preparing a batch of a mixture for which exemption from certification has been authorized; or

(5) when the package is reopened solely for repackaging by the person to whom such certificate was issued.

(e) A certificate shall not be effective with respect to a package of color additive and such color additive shall be considered to be from a batch that has not been certified if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by § 70.25 of this chapter to appear thereon.

(f) A certificate shall not be effective with respect to a package of color additive, and such color additive shall be considered to be from a batch that has not been certified if:

(1) Such package has not been sealed in accordance with § 70.20 of this chapter.

(2) Such package has been sealed in accordance with § 70.20 of this chapter and the seal has been broken, intentionally or accidentally, unless such seal has been broken for the purpose of using color additive in accordance with § 80.38, or, such package has been opened by a duly authorized representative of the Administration or Department in the performance of his official duties, and he has immediately resealed the package in conformance with § 70.20 of this chapter.

(g) A certificate shall not be effective with respect to a package of color additive and such color additive shall be considered to be from a batch that has not been certified if such color additive is used in any manner other than that for which it was certified.

(h) When the listing or the specifications for a color additive are revoked or amended, the final order effecting the revocation or amendment may specify, in addition to its own effective date, a date on which all certificates for existing batches and portions of batches of such a color additive theretofore issued under such revoked or amended regulations shall cease to be effective; and any such lots of the color additive shall be regarded as uncertified after the date specified unless a new certificate can be and is obtained in conformance with the new regulations. When a certificate thus ceases to be effective for a color additive, any certificates previously issued for a color additive mixture containing that color additive shall cease to be effective on the same date. Use of such color additive or color additive mixture after such specified date without the new certificate in preparing foods, drugs, or cosmetics will result in such food, drugs, or cosmetics being adulterated. When a certified color additive has been used in food, drugs, or cosmetics and the status of the color additive is thereafter changed by amendment or revocation of its listing or specification regulations, such food, drugs, and cosmetics will not be regarded as adulterated by reason of the use of such color additive, unless the hazard to health is such that existing stocks of the foods, drugs, or cosmetics cannot be safely used, in which cases findings to that effect will be made and regulations appropriate for such special cases will be issued.

§ 80.34 Authority to refuse certification service.

(a) When it appears to the Commissioner that a person has:

(1) Obtained, or attempted to obtain, a certificate through fraud or misrepresentation of a material fact.

(2) Falsified the records required to be kept by § 80.39; or

(3) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 80.39; or

(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

(b) Any person who contests suspension of service shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to Part 16 of this chapter.

§ 80.35 Color additive mixtures; certification and exemption from certification.

(a) *Color additive mixtures to be certified.* Any color additive mixture that contains one or more straight colors listed in Part 74 of this chapter, together with any diluents listed in such subparts for use with such straight colors, shall be certified if intended for use in foods, drugs, or cosmetics, or in coloring the human body, as the case may be, subject to any restriction prescribed in Parts 70 and 71 of this chapter.

(b) *Color additive mixtures exempted from certification.* A color additive mixture prepared from a previously certified batch of one or more straight colors, with or without any diluent that has been listed in Part 73 of this chapter for use in mixtures, shall be exempt from batch certification if the straight color used has not changed in composition in any manner whatsoever since its certification and if it is simply mixed with the approved diluents for exempt mixtures. The label of such color additive mixtures shall not bear the lot number assigned by the Food and Drug Administration to the certified straight color components, but shall bear the manufacturer's control number through which the history of the straight color can be determined.

(c) *Additions to the list of diluents.* A person requesting additions to the list of diluents authorized for the purposes described in paragraphs (a) and (b) of this section shall submit a petition in accordance with the provisions of § 71.1 of this chapter. Each such petition shall be accompanied by the fee prescribed in § 70.19 of this chapter, unless there is an advance deposit to be used for prepayment of such fees.

NOTE: The provisions of § 80.35 with respect only to diluents for use in cosmetic color additive mixtures were stayed, until a regulation is effected listing safe diluents for cosmetic use, including cosmetics which color the human body. 29 FR 18495, Dec. 29, 1964.

§ 80.37 Treatment of batch pending certification.

Immediately after the sample that is to accompany a request for certification of a batch of color additive is taken, the batch shall be:

(a) Stored in containers of such kind as to prevent change in composition.

(b) Held under the control of the person requesting certification until certified.

(c) Marked, by labeling or otherwise, in a manner such that there can be no question as to the identity of the batch and no question that it is not to be used until the requested certificate has been issued.

§ 80.38 Treatment of batch after certification.

(a) Immediately upon notification that a batch of color additive has been certified, the person requesting certification thereof shall identify such batch, by labeling, with the certified lot number.

(b) The person requesting certification shall maintain storage in such manner as to prevent change in composition until such batch has been packaged and labeled as required by §§ 70.20 and 70.25 of this chapter, except that the person requesting certification may use such color additive for the purpose of coloring a food, drug, or cosmetic.

§ 80.39 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health and Human Services, such person, at all reasonable hours until at least 2 years after disposal of all such color additive, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color additive on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Sec.
81.1 Provisional lists of color additives.
81.10 Termination of provisional listings of color additives.
81.27 Conditions of provisional listing.
81.30 Cancellation of certificates.
81.32 Limitation of certificates.

Authority: Secs. 701, 706, 52 Stat. 1055-1056 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); Title II, Pub. L. 86-618; sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note); 21 CFR 5.10.

Source: 42 FR 15665, Mar. 22, 1977, unless otherwise noted.

§ 81.1 Provisional lists of color additives.

The Commissioner of Food and Drugs finds that the following lists of color additives are provisionally listed under section 203(b) of the Color Additive Amendments of 1960 (sec. 203(b), 74 Stat. 405 (21 U.S.C. 376 note)). Except for color additives for which petitions have been filed, progress reports are required by January 1, 1968, and at 6-month intervals thereafter. Specifications for color additives listed in paragraphs (a), (b), and (c) of this section appear in the respective designated sections. The listing of color additives in this section is not to be construed as a listing for surgical suture use unless color additive petitions have been submitted for such use or the Commissioner has been notified of studies underway to establish the safety of the color additive for such use. The color additives listed in paragraphs (a), (b), and (c) of this section may not be used in products which are intended to be used in the area of the eye. The color additives listed in paragraphs (a), (b), (c), (f), and (g) of this section are provisionally listed until the closing dates set forth therein, conditioned on compliance with the applicable requirements of paragraphs (a), (b), (c), and (d) of § 81.27.

(a) *Color additives previously and presently subject to certification and provisionally listed for food, drug, and cosmetic use.*

Color additive	Closing date		Restrictions
	Food use	Drug and cosmetic use	
FD&C Red No. 3 (sec. 74.303 of this chapter).[1]	June 30, 1989	June 30, 1989	
Lakes (FD&C) (sec. 82.51 of this chapter).			

[1] Lakes only.

(b) *Color additives previously and presently subject to certification and provisionally listed for drug and cosmetic use.*

	Closing date	Restrictions
D&C Red No. 36 (sec. 82.1336 of this chapter).	Feb. 27, 1989	
Lakes (D&C) (Sec. 82.2051 of this chapter).		

(c) *Color additives previously and presently subject to certification and provisionally listed for use in externally applied drugs and cosmetics.*

	Closing date	Restrictions
Lakes (Ext. D&C) (sec. 82.105(1) of this chapter)		

(Sec. 706(b), (c), and (d), 74 Stat. 399-403 as amended; sec. 203(a)(2), (d)(1)(E), Pub. L. 86-618, 74 Stat. 404-407; 21 U.S.C. 376 note; secs. 701, 706(b), (c), and (d), 52 Stat. 1055-1056 as amended, 70 Stat. 919 as amended, 74 Stat. 399-403 (21 U.S.C. 371, 376(b), (c), and (d)); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note))

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For Federal Register citations affecting § 81.1, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 81.10 Termination of provisional listings of color additives.

(a) *Ext. D&C Yellow Nos. 9 and 10.* These colors cannot be produced with any assurance that they do not contain β-naphthylamine as an impurity. While it has been asserted that the two colors can be produced without the impurity named, no method of analysis has been suggested to establish the fact. β-Naphthylamine is a known carcinogen; therefore, there is no scientific evidence that will support a safe tolerance for these colors in products to be used in contact with the skin. The Commissioner of Food and Drugs, having concluded that such action is necessary to protect the public health, hereby terminated the provisional listing of Ext. D&C Yellow No. 9 and Ext. D&C Yellow No. 10.

(b) [Reserved]

(c) *FD&C Red No. 1.* Results of recent feeding tests of this color additive have demonstrated it to be toxic upon ingestion:

(1) Groups of 50 rats are being fed diets containing FD&C Red No. 1 at levels of 5 percent, 2 percent, 1 percent, 0.5 percent, and 0 percent. At this stage of the tests, which have now been in progress for from 15 months to 18 months, 116 animals from the 250 being fed FD&C Red No. 1 at various levels and 27 of the 100 controls have died. Of these, 11 being fed at the 5 percent level, 16 being fed at the 2 percent level, 11 being fed at the 1 percent level, and 2 being fed at the 0.5 percent level, have shown liver

damage. None of the controls that have died have shown liver damage.

(2) Groups of 100 mice are being fed diets containing 2 percent, 1 percent, 0.5 percent, and 0.1 percent FD&C Red No. 1, with 400 mice as controls. All mice on dosage levels of 2 percent and 1 percent died before the seventieth week. Gross liver damage has been observed in all groups fed at the 0.5 percent diet and above.

(3) Groups of 4 dogs are being fed diets containing 2 percent, 1 percent, 0.25 percent, and 0 percent FD&C Red No. 1. Three of the dogs on the 2 percent dosage level died before 32 weeks; the other is living. Three of the dogs on the 1 percent dosage level died or were sacrificed within 13 months. All deceased or sacrificed dogs have shown liver damage grossly and/or microscopically. Deceased dogs on the 1 percent and 2 percent dosage level showed poor physical condition.

The Commissioner of Food and Drugs having concluded that ingestion of this color additive over a long period of time would be unsafe, and in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 1 for use in foods, drugs, and cosmetics.

(d) *FD&C Red No. 4.* Feeding tests of this color additive have been conducted with three species:

(1) Rats of the Osborne-Mendel and Sprague-Dawley strains were fed FD&C Red No. 4 for 2 years at levels of 5 percent, 2 percent, 1 percent, and 0.5 percent of the diet. No effect was found.

(2) Mice of the C3Hf and C57BL strains were fed FD&C Red No. 4 for 2 years at levels of 2 percent and 1 percent of the diet. No effect was found.

(3) Dogs were fed FD&C Red No. 4 at levels of 2 percent and 1 percent of the diet. Adverse effects were found at both levels in the urinary bladder and in the adrenals. Three dogs of five fed on the 2-percent level died after 6 months, 9 months, and 5½ years on the test. Two of the dogs on the 2-percent level and all five of the dogs on the 1-percent level survived to the completion of the 7 year study.

The Commissioner of Food and Drugs has concluded that available data do not permit the establishment of a safe level of use of this color additive in food, ingested drugs and ingested cosmetics. In order to protect the public health, the Commissioner hereby terminates the provisional listing of FD&C Red No. 4 for use in food and ingested drugs. The Commissioner has previously terminated the provisional listing of FD&C Red No. 4 for use in ingested cosmetics. FD&C Red No. 4 is listed for use in externally applied drugs and cosmetics by §§ 74.1304 and 74.2304 of this chapter, respectively. Section 82.304 of this chapter is retained in Part 82 of this chapter to permit the use of lakes of FD&C Red No. 4 in externally applied drugs and cosmetics.

(e) *FD&C Violet No. 1.* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of FD&C Violet No. 1 for use in foods, drugs, and cosmetics.

(f) *FD&C Red No. 2.* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of FD&C Red No. 2 for use in food, drugs, and cosmetics.

(g) *Carbon black (prepared by the "impingement" or "channel" process).* The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of carbon black (prepared by the "impingement" or "channel" process) for use in food, drugs, and cosmetics.

(h) *D&C Red Nos. 10, 11, 12, and 13.* The petition for these color additives was withdrawn so that there no longer exists a basis for their continued provisional listing. In addition, the Commissioner has learned of the possible contamination of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 with β-naphthylamine. The Commissioner concludes that these colors cannot be produced with any reasonable assurance that they will not contain β-naphthylamine as an impurity or not yield β-naphthylamine from the metabolism of subsidiary colors present in them. β-Naphthylamine is a known carcinogen; therefore, there is no scientific evidence that will support a safe tolerance for these colors in drugs or cos metics. The Commissioner of Food and Drugs, upon withdrawal of the petition for their use and in order to protect the public health, hereby terminates the provisional listing of D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13 for use in drugs and cosmetics, effective December 13, 1977.

(i) *Ext. D&C Yellow No. 1.* The Commissioner has learned of the contamination of Ext. D&C Yellow No. 1 with 4-aminobiphenyl. The Commissioner concludes that this color cannot be produced with any reasonable assurance that it will not contain 4-aminobiphenyl as an impurity or not yield benzidine from the decomposition of a subsidiary reaction product that might be present in the color. 4-Aminobiphenyl and benzidine are known carcinogens; therefore, there is no scientific evidence that will support a safe tolerance for these colors in drugs or cosmetics. In addition, insufficient data have been submitted to permit establishment of appropriate specifications for the batch certification of the color. The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of Ext. D&C Yellow No. 1 for use in externally applied drugs and cosmetics, effective December 13, 1977.

(j) *Graphite.* Data have been developed that show the contamination of graphite with polynuclear aromatic hydrocarbons (PNA's). There is no reasonable assurance this color can be produced so that it will not contain PNA's as an impurity. The presence of certain PNA's in graphite would indicate that PNA's known to be carcinogenic to animals and humans may also be present. Therefore, there is no scientific evidence that will support a safe tolerance for this color in drugs or cosmetics. The Commissioner of Food and Drugs, in order to protect the public health, hereby terminates the provisional listing of graphite for use in externally applied cosmetics, effective November 29, 1977.

(k) *Ext. D&C Green No. 1.* The Commissioner concludes that there are inadequate analytical methods to permit certification of the color additive Ext. D&C Green No. 1. In addition, the Commissioner has found that there was a failure to comply with the conditions attached to the postponement of the closing date in accordance with section 203(a)(2) of the transitional provisions of the Color Additive Amendments of 1960. The Commissioner of Food and Drugs hereby terminates the provisional listing of Ext. D&C Green No. 1 for use in externally applied drugs and cosmetics, effective November 29, 1977.

(l) [Reserved]

(m) *D&C Orange Nos. 10 and 11.* In the absense of a petition to list D&C Orange No. 10 and D&C Orange No. 11 for use in ingested drugs and cosmetics, there no longer exists a basis for provisional listing for such uses. Therefore, FDA is terminating the provisional listing of D&C Orange No. 10 and D&C Orange No. 11 for use in ingested drugs and cosmetics, effective April 28, 1981.

(n) *D&C Blue No. 6.* The Commissioner of Food and Drugs, having concluded that unresolved questions remain concerning the chemistry of unidentified minor components, hereby terminates the provisional listing of D&C Blue No. 6 for use in drugs and cosmetics.

(o) *D&C Green No. 6.* In the absence of a petition to list D&C Green No. 6 for use in ingested drugs and cosmetics, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listing of D&C Green No. 6 for use in ingested drugs and cosmetics, effective March 27, 1981.

(p) [Reserved]

(q)(1) *D&C Red No. 19 and D&C Red No. 37.* Having concluded that, when ingested, D&C Red No. 19 causes cancer in rats and mice, the agency hereby terminates the provisional listings of D&C Red No. 19 and chemically related D&C Red No. 37 for use in ingested drugs and ingested cosmetics, effective February 4, 1983.

(2) *D&C Red No. 37.* In the absence of a petition to list D&C Red No. 37 for external uses, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listings of

D&C Red No. 37 for use in externally applied drugs and cosmetics, effective June 6, 1986.

(r) [Reserved]

(s) *D&C Orange No. 17.* Having concluded that, when ingested, D&C Orange No. 17 causes cancer in rats and mice, the agency has terminated the provisional listing of D&C Orange No. 17 for use in ingested drugs and ingested cosmetics, effective March 31, 1983.

(t) *D&C Red No. 8 and D&C Red No. 9.* In the absence of a petition to list D&C Red No. 8 and D&C Red No. 9 for mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, there no longer exists a basis for provisional listing for such uses. Accordingly, the Commissioner of Food and Drugs hereby terminates the provisional listings of D&C Red No. 8 and D&C Red No. 9 for use in mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, effective January 6, 1987.

(Sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d)), and title II, Pub. L 86-618; sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note)

[42 FR 15665, Mar. 22, 1977]

EDITORIAL NOTE: For Federal Register citations affecting § 81.10, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 81.27 Conditions of provisional listing.

(a)—(c) [Reserved]

(d) The closing dates and dates for final reports for the following 10 color additives are postponed in accordance with the following list while chronic toxicity feeding studies are conducted and evaluated and subject to compliance with the requirements of this paragraph:

	Final report due	Closing date
FD&C Red No. 3		June 30, 1989
D&C Red No. 36		Feb. 27, 1989

(1) At least one petitioner for each of the 25 color additives listed in paragraph (d) of this section shall agree in writing by March 7, 1977 to undertake the required studies on the color additives.

(2) The petitioner undertaking the studies shall submit a protocol for the conduct of the studies to the Division of Food and Color Additives (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204, for review and acceptance or rejection, by April 5, 1977.

(3) An initial progress report of the studies on the color additives shall be submitted to the Division of Food and Color Additives by December 31, 1977. Further progress reports shall be submitted at 6-month intervals thereafter.

(4) The petitioners undertaking the studies shall immediately notify the Division of Food and Color Additives of any findings that indicate potential for the color additives to cause adverse effects.

(Title II, Pub. L. 86-316, Pub. L. 86-618; sec. 203, 74 Stat. 399-407 as amended; sec. 706(b), (c), and (d) (21 U.S.C. 376(b), (c), and (d), and note) secs. 706(b), (c), and (d), 74 Stat. 399—403 (21 U.S.C. 371(e), 376(b), (c), (d)); sec. 203, 74 Stat. 404—407 (21 U.S.C. 376 note); secs. 701, 706(b), (c), and (d), 52 Stat. 1055-1056 as amended, 74 Stat. 399-403 (21 U.S.C. 371, 376(b), (c), and (d)); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note; 70 Stat. 919, as amended))

[43 FR 14643, Apr. 7 1978]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 81.27, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 81.30 Cancellation of certificates.

(a) Certificates issued heretofore for colors being removed from the provisional list (§ 81.10(a)) are cancelled and of no effect after December 1, 1960, and use of such color additives in drugs or cosmetics after that date will result in adulteration.

(b)(1) Certificates issued heretofore for the color additive designated FD&C Red No. 1 are cancelled as of the date of the publication of this Order, and use of this color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence

before him, taking into account that the additive is not an acute toxic substance and that it is only used in small amounts in foods, drugs, and cosmetics.

(c) Certificates issued for FD&C Red No. 4 and all mixtures containing this color additive are cancelled and have no effect after September 23, 1976 insofar as food, ingested drugs, and ingested cosmetics are concerned, and use of this color additive in the manufacture of food, ingested drugs, and ingested cosmetics after this date will result in adulteration. The certificates shall continue in effect for the use of FD&C Red No. 4 in externally applied drugs and cosmetics. The Commissioner finds, on the basis of the scientific evidence before him that no action has to be taken to remove from the market food, ingested drugs and ingested cosmetics containing the color additive.

(d) Certificates issued for the following color additives and all mixtures containing these color additives are canceled and have no effect after October 4, 1966, and use of such color additives in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration:

FD&C Green No. 1.
FD&C Green No. 2.
D&C Green No. 7.
D&C Red No. 5.
D&C Red No. 14.
D&C Red No. 18.
D&C Red No. 24.
D&C Red No. 29.
D&C Red No. 35.
D&C Red No. 38.
D&C Orange No. 3.
D&C Orange No. 8.
D&C Orange No. 14.
D&C Orange No. 15.
D&C Orange No. 16.
D&C Blue No. 7.
D&C Black No. 1.
Ext. D&C Yellow No. 5.
Ext. D&C Yellow No. 6.
Ext. D&C Red No. 1.
Ext. D&C Red No. 2.
Ext. D&C Red No. 3.
Ext. D&C Red No. 10.
Ext. D&C Red No. 11.
Ext. D&C Red No. 13.
Ext. D&C Red No. 14.
Ext. D&C Red No. 15.
Ext. D&C Blue No. 1.
Ext. D&C Blue No. 4.
Ext. D&C Orange No. 1.
Ext. D&C Orange No. 4.

(e) Certificates issued for the following color additives and all mixtures containing these color additives are canceled and have no effect after July 1, 1968, and use of such color additives in the manufacture of drugs or cosmetics after that date will result in adulteration:

Ext. D&C Yellow No. 3.
Ext. D&C Red No. 8
Ext. D&C Orange No. 3.

(f) Certificates issued for D&C Yellow No. 11 and all mixtures containing this color additive are canceled and have no effect after April 30, 1968, insofar as ingested use is concerned. Use of this color additive in the manufacture of ingested drugs or cosmetics subject to ingestion after that date will result in adulteration.

(g) Certificates issued for D&C Red No. 17, D&C Red No. 31, D&C Red No. 34, D&C Orange No. 4, and D&C Violet No. 2, and all mixtures containing these color additives, are canceled and have no effect after December 31, 1968, insofar as ingested use is concerned. Use of these color additives in the manufacture of ingested drugs or cosmetics subject to ingestion after that date will result in adulteration.

(h)(1) Certificates issued for FD&C Violet No. 1 and all mixtures containing this color additive are canceled and have no effect after April 10, 1973, and use of such color additive in the manufacture of foods, drugs, or cosmetics after that date will result in adulteration.

(2) The Commissioner finds that no action needs to be taken to remove foods, drugs, and cosmetics containing this color additive from the market on the basis of the scientific evidence before him.

(i) Certificates issued prior to July 1, 1968, for D&C Brown No. 1 and Ext. D&C Violet No. 2 and all mixtures containing these colors are canceled and have no effect. This cancellation does not apply to certificates issued after March 15, 1973, for D&C Brown No. 1 and Ext. D&C Violet No. 2, which are provisionally listed in § 81.1(b) and (c) respectively for coloring externally applied cosmetics.

(j)(1) Certificates issued for FD&C Red No. 2 and all mixtures containing this color additive are canceled and have no effect after January 28, 1976, and use of this color additive in the manufacture of food, drugs, or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market food, drugs, and cosmetics containing the color additive.

(k)(1) Certificates issued for D&C Red No. 10, D&C Red No. 11, D&C Red No. 12, and D&C Red No. 13, their lakes and all mixtures containing these color additives or their lakes are cancelled and have no effect after December 13, 1977, and use of these color additivies in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market, drug and cosmetic products containing the color additives.

(l)(1) Certificates issued for Ext. D&C Yellow No. 1 and all mixtures containing this color additive are cancelled and have no effect after December 13, 1977, and use of this color additive in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(m)(1) Certificates issued for Ext. D&C Green No. 1 and all mixtures containing this color additive are cancelled and have no effect after November 29, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(n)(1) Certificates issued for D&C Orange No. 10, D&C Orange No. 11, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after April 28, 1981 and use of these color additives in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market drugs and cosmetics to which the color additives were added on or before April 28, 1981.

(o)(1) Certificates issued for D&C Blue No. 6 and all mixtures containing this color additive are cancelled insofar as its use in drugs and cosmetics is concerned and have no effect after December 13, 1977, and use of the color additive in the manufacture of drugs or cosmetics after this date will result in adulteration. The color will continue to be certified for use in the coloring of surgical sutures.

(2) The Commissioner finds, on the basis of the scientific evidence before him, that no action has to be taken to remove from the market drugs and cosmetics containing the color additive.

(p)(1) Certificates issued for D&C Green No. 6, its lakes and all mixtures containing this color additive are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after May 4, 1982 and use of the color additive in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market ingested drugs and cosmetics containing the color additive.

(q) [Reserved]

(r)(1) Certificates issued for D&C Red No. 19 and D&C Red No. 37, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drugs and cosmetics after February 4, 1983, and use of these color additives in the manufacture of ingested drugs or cosmetics after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market ingested drugs and cosmetics to which D&C Red No. 19 and D&C Red No. 37 were added on or before February 4, 1983, or externally applied drugs and cosmetics to which D&C Red No. 37 was added on or before June 6, 1986.

(3) Certificates issued for D&C Red No. 37, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after June 6, 1986, and use of this color additive in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(4) Certificates issued for D&C Red No. 19, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after July 15, 1988, and use of this color in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(5) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market externally applied drugs and cosmetics to which D&C Red No. 19 was added on or before July 15, 1988.

(s)(1) Certificates issued for D&C Red No. 8 and D&C Red No. 9, their lakes, and all mixtures containing these color additives are canceled and have no effect as pertains to their use in mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, after January 6, 1987, and use of these color additives in the manufacture of mouthwash, dentifrices, and ingested drugs, except ingested drug lip products, after this date will result in adulteration.

(2) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market mouthwash, dentifrices, and ingested drugs to which the color additives were added on or before January 6, 1987. Ingested drug lip products, however, are regulated for use in §§ 74.1308 and 74.1309.

(3) Certificates issued for D&C Red No. 8, and D&C Red No. 9, their lakes, and all mixtures containing these color additives are cancelled and have no effect as pertains to their use in ingested drug and cosmetic lip products and in externally applied drugs and cosmetics after July 15, 1988, and use of these color additives in the manufacture of ingested drugs and cosmetic lip products and in externally applied drugs and cosmetics after this date will result in adulteration.

(4) The agency finds, on the basis of the scientific evidence before it, that no action has to be taken to remove from the market ingested drug and cosmetic lip products and externally applied drugs and cosmetics to which the color additives were added on or before July 15, 1988.

(t)(1) Certificates issued for D&C Orange No. 17, its lakes, and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in ingested drugs and ingested cosmetics after March 31, 1983 and use of this color additive in the manufacture of ingested drugs or ingested cosmetics after this date will result in adulteration.

(2) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market drugs and cosmetics to which the color additive was added on or before March 31, 1983.

(3) Certificates issued for D&C Orange No. 17, its lakes and all mixtures containing this color additive are cancelled and have no effect as pertains to its use in externally applied drugs and cosmetics after July 15, 1988, and use of this color in the manufacture of externally applied drugs or cosmetics after this date will result in adulteration.

(4) The agency finds, on the scientific evidence before it, that no action has to be taken to remove from the market externally applied drugs and cosmetics to which D&C Orange No. 17 was added on or before July 15, 1988.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[42 FR 15665, Mar. 22, 1977, as amended at 42 FR 60737, Nov. 29, 1977; 42 FR 62474, Dec. 13, 1977; 42 FR 62477, Dec. 13, 1977; 42 FR 62482, Dec. 13, 1977; 46 FR 18954, Mar. 27, 1981; 47 FR 14147, Apr. 2, 1982; 48 FR 5264, Feb. 4,1983; 48 FR 13978, Apr. 1, 1983; 49 FR 13343, Apr. 4, 1984; 51 FR 20788, June 6, 1986; 51 FR 43899, Dec. 5, 1986; 52 FR 902, Jan. 9, 1987; 53 FR 26768 and 26770, July 15, 1988]

§ 81.32 Limitation of certificates.

Certificates issued for the color additives listed in § 81.25 and for all mixtures containing these color additives are limited to the conditions stated in § 81.25. The use of these color additives in drugs and cosmetics in any other manner will result in adulteration. Each of these color additives shall bear a label statement of the tolerance and use limitations applicable to it.

(Sec. 203(d)(1)(C), 74 Stat. 405 (21 U.S.C. 376 note))

[44 FR 48966, Aug. 21, 1979]

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

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Subpart D—Externally Applied Drugs and Cosmetics

82.2050 General.
82.2051 Lakes (Ext. D&C).
82.2707a Ext. D&C Yellow No. 7.

AUTHORITY: Secs. 701, 706, 52 Stat. 1055-1056 as amended. 74 Stat. 399-407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

SOURCE: 42 FR 15669, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 82.3 Definitions.

For the purposes of this part:

(a)—(f) [Reserved]

(g) The term "alumina" means a suspension in water of precipitated aluminum hydroxide.

(h) The term "blanc fixe" means a suspension in water of precipitated barium sulfate.

(i) The term "gloss white" means a suspension in water of co-precipitated aluminum hydroxide and barium sulfate.

(j) The term "mixed oxides" means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k)—(m) [Reserved]

(n) The term "externally applied drugs and cosmetics" means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o)—(p) [Reserved]

(q) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in this part.

§ 82.5 General specifications for straight colors.

No batch of a straight color listed in Subpart B, C, or D shall be certified under this part unless:

(a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such paragraph for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in Subpart B:

(i) Lead (as Pb), not more than 0.001 percent.

(ii) Arsenic (as As_2O_3), not more than 0.00014 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in Subpart C or D:

(i) Lead (as Pb), not more than 0.002 percent.

(ii) Arsenic (as As_2O_3), not more than 0.0002 percent.

(iii) Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in Subpart C or D—soluble barium (in dilute HCl) (as $BaCl_2$), not more than 0.05 percent.

§ 82.6 Certifiable mixtures.

(a) A batch of a mixture which contains no straight color listed in Subpart C or D may be certified for use in food, drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) Each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) No diluent (except resins, natural gum, pectin and, in the case of mixtures which are aqueous solutions or aqueous pastes, sodium benzoate in a quantity of not more than ⅒ of 1 percent) in such mixture is a nonnutritive substance, unless such mixture is for external application to shell eggs, or for use in coloring a food specified in the requests for certification of such batch submitted in accordance with § 80.21 of this chapter, and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in Subpart D, or which contains a diluent not permitted by paragraph (a)(3) of this section, may be certified in accordance with the provisions of this part, for use only in drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture.

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

(c) A batch of a mixture which contains a straight color listed in Subpart D may be certified in accordance with the provisions of this part, for use only in externally applied drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture; and

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

Subpart B—Foods, Drugs, and Cosmetics

§ 82.50 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of the regulations in this part, for use in food, drugs, and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications in this subpart set forth for such color.

§ 82.51 Lakes (FD&C).

(a)(1) *General.* Any lake made by extending on a substratum of alumina, a salt prepared from one of the certified water-soluble straight colors hereinbefore listed in this subpart by combining such color with the basic radical aluminum or calcium.

(2) *Specifications.*

Prepared from previously certified colors listed in this subpart.

Soluble chlorides and sulfates (as sodium salts), not more than 2.0 percent.

Inorganic matter, insoluble HCl, not more than 0.5 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radical combined in such color; and

(3) The word "Lake".

(For example, the name of a lake prepared by extending the aluminum salt prepared from FD&C Blue No. 1 upon the substratum would be FD&C Blue No. 1—Aluminum Lake.)

§ 82.101 FD&C Blue No. 1.

The color additive FD&C Blue No. 1 shall conform in identity and specifications to the requirements of § 74.101(a)(1) and (b) of this chapter.

§ 82.102 FD&C Blue No. 2.

The color additive FD&C Blue No. 2 shall conform in identity and specifications to the requirements of § 74.102(a)(1) and (b) of this chapter.

[48 FR 5261, Feb. 4, 1983]

§ 82.203 FD&C Green No. 3.

The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b) of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 52144, Nov. 19, 1982]

§ 82.303 FD&C Red No. 3.

The color additive FD&C Red No. 3 shall conform in identity and specifications to the requirements of § 74.303(a)(1) and (b) of this chapter.

§ 82.304 FD&C Red No. 4.

The color additive FD&C Red No. 4 shall conform in identity and specifications to the requirements of § 74.1304(a)(1) and (b) of this chapter. FD&C Red No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.705 FD&C Yellow No. 5.

The color additive FD&C Yellow No. 5 shall conform in identity and specifications to the requirements of § 74.705 (a)(1) and (b) of this chapter.

[51 FR 24519, July 7, 1986]

§ 82.706 FD&C Yellow No. 6.

(a) The color additive FD&C Yellow No. 6 shall conform in identity and specifications to the requirements of § 74.706 (a)(1) and (b) of this chapter.

(b) All lakes including current D&C external and D&C lakes of FD&C Yellow No. 6 shall be manufactured from previously certified batches of the straight color additive.

[52 FR 21509, June 8, 1987]

Subpart C—Drugs and Cosmetics

§ 82.1050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use only in drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

§ 82.1051 Lakes (D&C).

(a)(1) *General.* Any lake, other than those listed in Subpart B, made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or any combination of two or more of these, (i) one of the straight colors (except lakes) listed in Subpart B or hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium; or (ii) a salt prepared from one of the straight colors (except lakes) listed in Subpart B, or hereinbefore listed in this subpart, by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared, except that if such name contains the symbol "FD&C" such symbol shall be changed to "D&C";

(2) The name of the basic radical combined in such color; and

(3) The word "Lake."

(For example, the name of a lake prepared by extending the color D&C Red No. 9 upon a substratum is "D&C Red No. 9—Barium Lake", and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum other than alumina is "D&C Green No. 1—Aluminum Lake".)

§ 82.1104 D&C Blue No. 4.

The color additive D&C Blue No. 4 shall conform in identity and specifications to the requirements of § 74.1104(a)(1) and (b) of this chapter. D&C Blue No. 4 is restricted to use in externally applied drugs and cosmetics.

§ 82.1205 D&C Green No. 5.

The color additive D&C Green No. 5 shall conform in identity and specifications to the requirements of § 74.1205(a)(1) and (b)(2) of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 24285, June 4, 1982]

§ 82.1206 D&C Green No. 6.

The color additive D&C Green No. 6 shall conform in identity and specifications to the requirements of § 74.1206 (a) and (b) of this chapter. D&C Green No. 6 is restricted to use in externally applied drugs and cosmetics.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 14147, Apr. 2, 1982, as amended at 51 FR 9785, Mar. 21, 1986]

§ 82.1254 D&C Orange No. 4.

The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254(a)(1) and (b) of this chapter. D&C Orange No. 4 is restricted to use in externally applied drugs and cosmetics.

[42 FR 52396, Sept. 30, 1977]

§ 82.1255 D&C Orange No. 5.

(a) The color additive D&C Orange No. 5 shall conform in identity and specifications to the requirements of § 74.1255(a)(1) and (b) of this chapter. D&C Orange No. 5 is restricted to the uses described in this section.

(b) The color additive D&C Orange No. 5. may be safely used for coloring externally applied drugs in amounts not exceeding 5 milligrams per daily dose of the drug. The color additive D&C Orange No. 5 may be safely used for coloring lipsticks and other cosmetics intended to be applied to the lips in amounts not exceeding 5.0 percent by weight of the finished cosmetic products, and for coloring mouthwashes, dentifrices, and externally applied cosmetics in amounts consistent with current good manufacturing practice.

(Sec. 706(b), (c), and (d)), 74 Stat. 399-403 (21 U.S.C. 376(b), (c), and (d)))

[49 FR 13343, Apr. 4, 1984]

§ 82.1260 D&C Orange No. 10.

The color additive D&C Orange No. 10 shall conform in identity and specifications to the requirements to § 74.1260(a)(1) and (b) of this chapter. D&C Orange No. 10 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

§ 82.1261 D&C Orange No. 11.

The color additive D&C Orange No. 11 shall conform in identity and specifications to the requirements of § 74.1261(a)(1) and (b) of this chapter. D&C Orange No. 11 is restricted to use in externally applied drugs and cosmetics.

[46 FR 18954, Mar. 27, 1981]

§ 82.1306 D&C Red No. 6.

(a) The color additive D&C Red No. 6 shall conform in identity and specifications to the requirements of § 74.1306 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 6 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(Sec. 706 (b), (c), (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 57691, Dec. 28, 1982]

§ 82.1307 D&C Red No. 7.

(a) The color additive D&C Red No. 7 shall conform in identity and specifications to the requirements of § 74.1307 (a)(1) and (b) of this chapter.

(b) The color additive D&C Red No. 7 may be safely used for coloring drugs such that the combined total of D&C Red No. 6 and D&C Red No. 7 does not exceed 5 milligrams per daily dose of the drug.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 57691, Dec. 28, 1982]

§ 82.1317 D&C Red No. 17.

The color additive D&C Red No. 17 shall conform in identity and specifications to the requirements of § 74.1317 (a)(1) and (b) of this chapter. D&C Red No. 17 is restricted to use in externally applied drugs and cosmetics.

§ 82.1321 D&C Red No. 21.

The color additive D&C Red No. 21 shall conform in identity and specifications to the requirements of § 74.1321 (a)(1) and (b) of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 53847, Nov. 30, 1982]

§ 82.1322 D&C Red No. 22.

The color additive D&C Red No. 22 shall conform in identity and specifications to the requirements of § 74.1322 (a)(1) and (b) of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 53847, Nov. 30, 1982]

§ 82.1327 D&C Red No. 27.

The color additive D&C Red No. 27 shall conform in identity and specifications to the requirements of § 74.1327 (a)(1) and (b) of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 42568, Sept. 28, 1982]

§ 82.1328 D&C Red No. 28.

The color additive D&C Red No. 28 shall conform in identity and specifications to the requirements of § 74.1328 (a)(1) and (b) of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 42568, Sept. 28, 1982]

§ 82.1330 D&C Red No. 30.

The color additive D&C Red No. 30 shall conform in identity and specifications to the requirements of § 74.1330 (a)(1) and (b) of this chapter.

(Secs. 706(b), (c), and (d), 74 Stat 399-403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub.

L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[47 FR 22511, May 25, 1982]

§ 82.1331 D&C Red No. 31.

The color additive D&C Red No. 31 shall conform in identity and specifications to the requirements of § 74.1331(a)(1) and (b) of this chapter. D&C Red No. 31 is restricted to use in externally applied drugs and cosmetics.

§ 82.1333 D&C Red No. 33.

(a) The color additive D&C Red. No. 33 shall conform in identity and specifications to the requirements of § 74.1333(a) (1) and (b) of this chapter.

(b) All lakes of D&C Red. No. 33 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 33121, Aug. 30, 1988]

§ 82.1334 D&C Red No. 34.

Calcium salt of 3-hydroxy-4-[(1-sulfo-2 -naphthalenyl)azo]-2 naphthalenecarboxylic acid.

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

2-Amino-1-naphthalenesulfonic acid, calcium salt, not more than 0.2 percent.

3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.

Subsidiary colors, not more than 4 percent.

Total color not less than 85 percent.

§ 82.1336 D&C Red No. 36.

(a) The color additive D&C Red No. 36 shall conform in identity and specifications to the requirements of § 74.1336 (a)(1) and (b) of this chapter.

(b) All lakes of D&C Red No. 36 shall be manufactured from previously certified batches of the straight color additive.

[53 FR 29031, Aug. 2, 1988]

§ 82.1602 D&C Violet No. 2.

The color additive D&C Violet No. 2 shall conform in identity and specifications to the requirements of § 74.1602(a)(1) and (b) of this chapter.

§ 82.1707 D&C Yellow No. 7.

The color additive D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

§ 82.1708 D&C Yellow No. 8.

The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1707(a)(1) and (b) of this chapter. D&C Yellow No. 8 is restricted to use in externally applied drugs and cosmetics.

§ 82.1710 D&C Yellow No. 10.

The color additive D&C Yellow No. 10 shall conform in identity and specifications to the requirements of § 74.1710(a)(1) and (b) of this chapter.

(Sec. 706(b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376(b), (c), and (d); sec. 203, Pub. L. 86-618, 74 Stat. 404-407 (21 U.S.C. 376, note))

[48 FR 39220, Aug. 30, 1983]

Subpart D—Externally Applied Drugs and Cosmetics

§ 82.2050 General.

A batch of a straight color listed in this subpart may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of § 82.5 and to the specifications set forth in this subpart for such color.

§ 82.2051 Lakes (Ext. D&C).

(a)(1) *General.* Any lake made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, calcium carbonate, or on any combination of two or more of these (i) one of the straight colors hereinbefore listed in this subpart, which color is a salt in which is combined the basic radical sodium, potassium, barium, or calcium; or (ii) a salt prepared from one of the straight colors hereinbefore listed in this subpart by combining such color with the basic radical sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

(2) *Specifications.*

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radical combined in such color; and

(3) The word "Lake." (For example, the name of a lake prepared by extending the color Ext. D&C Yellow No. 2 upon a substratum is "Ext. D&C Yellow No. 2—Calcium Lake," and a lake prepared by extending the barium salt prepared from Ext. D&C Red No. 2 upon the substratum is "Ext. D&C Red No. 2—Barium Lake.")

§ 82.2707a Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity with specifications to the requirements of § 74.1707a(a)(1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

PARTS 83–99 [RESERVED]

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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Material Approved for Incorporation by Reference

(Revised as of March 31, 1989)

The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR Part 51 the incorporation by reference of the following publications. This list contains only those incorporations by reference effective as of the revision date of this volume. Incorporations by reference found within a regulation are effective upon the effective date of that regulation. For more information on incorporation by reference, see the preliminary pages of this volume.

21 CFR CHAPTER I (PARTS 1 TO 99)

FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

	21 CFR
Association of Official Analytical Chemists	
P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044	
Official Methods of Analysis, 13th Ed., 1980	2.19
NOTE: The following materials are available through the Food and Drug Administration at the addresses indicated.	
Bureau of Foods (HFF–330), Food and Drug Administration	
200 C St. SW., Washington DC 20204	
Measure Container Code of the National Bureau of Standards Handbook 44 "Sec. 4.45 Measure-Containers".	1.24(a)(6)(i), (ii) and (iii)
National Academy Press	
2101 Constitution Ave., N.W., Washington, D.C. 20418	
Food Chemicals Codex, 3d Ed (1981)	73.160 (a) and (b); 73.450 (a) and (b)

best copy available

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At 40 FR 13996, March 27, 1975, a document was published representing a reorganization of material remaining in Subchapter C—Drugs that has general applicability, rather than strictly human or animal use. In addition certain related sections under Parts 1 and 3 were redesignated as parts of the revised Subchapter C—Drugs: General.

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3.90	250.300
3.91	250.250
3.94	250.109
3.95	250.110
3.501	200.5
3.502	201.19
3.503	201.312
3.505	201.313
3.506	200.11
3.507	201.17
3.508	201.18
3.509	201.314
3.510	201.315
3.512	200.31
3.513	200.7
3.514	201.55
3.515	201.160
3.516	250.105
3.518	201.161

Redesignation Table II

At 41 FR 24262, June 15, 1976, a document was published recodifying the delegation of authority and organizational statement portions of the general regulations.

The following table shows the relationship of the CFR section numbers under the former Subparts H and M of Part 2 to their redesignation reflected in new Part 5:

Old section	New section
2.120	5.1
2.121 [1]	5.20
2.121(b)	5.21
2.121(c)	5.22
2.121(d)	5.23
2.121(e)	5.24
2.121(f)	5.25
2.121(h)	5.26
2.121(i)	5.27
2.121(j)	5.28
2.121(k)	5.30
2.121(l)	5.31
2.121(m)	5.29
2.121(n)	5.32
2.121(o)	5.33
2.121(p)	5.34
2.121(q)	5.35
2.121(r)	5.36
2.121(s)	5.37
2.121(t)	5.38
2.121(u)	5.39
2.121(v)	5.40
2.121(w)	5.41
2.121(x)	5.42
2.121(z)	5.43
2.121(aa)	5.44
2.121(bb)	5.45
2.121(cc)	5.46
2.121(dd)	5.47
2.121(ee)	5.48
2.121(ff)	5.49
2.121(gg)	5.50
2.121(hh)	5.51
2.121(ii)	5.52
2.171	5.100
2.172	5.105
2.173	5.110
2.175	5.115

[1] Introductory text and paragraph (a).

Redesignation Table III

At 42 FR 14302, March 15, 1977, regulations formerly under Subchapter A and those sections being redesignated under the reorganized Subchapter B and Subchapter E were reorganized and republished.

For the convenience of the user, the following table includes all changes made by FDA recodification documents numbered 14 (41 FR 38618, Sept. 10, 1976) and 15 (42 FR 14302, March 15, 1977; 42 FR 56728, Oct. 28, 1977; 43 FR 1941, Jan. 13, 1978).

Old section	New human section	New animal section[1]
1.7	101.1	501.1
1.8	101.3	501.3
1.8a	10.5	501.5
1.8b	101.105	501.105
1.8c	101.8	501.8
1.8d	101.2	501.2
1.9	101.15	501.15
1.10	101.4	501.4
1.10a	101.100	501.100
1.10b	101.103	501.103
1.12	101.22	501.22
1.13	101.17	501.17
1.15	101.18	501.18
1.16	NA	501.110
1.17	101.9	NA
1.18	101.25	NA
3.2	100.150	NA
3.5	100.135	NA
3.17	166.40	NA
3.19	133.10	NA
3.20	100.160	NA
3.23	101.35	NA
3.24	100.145	NA
3.31	100.140	NA
3.38	161.30	NA
3.51	101.33	NA
3.69	100.120	NA
3.72	100.130	NA
3.87	100.155	NA
3.88	101.6	NA
3.93	109.15	509.15
3.202	101.29	NA
3.206	131.25	NA
3.207	101.10	NA
10.1	130.3	564.3
10.2	130.5	564.5
10.3	130.8	564.8
10.4	130.20	564.20
10.5	130.17	564.17
10.6	130.12	564.12
10.7	130.14	564.14
10.8	130.6	564.6
11.1	103.5	NA
11.2	103.3	NA
11.5	103.23	NA
11.6	103.29	NA
11.7	103.35	NA
14.1	163.110	NA
14.2	163.111	NA
14.3	163.112	NA
14.4	163.113	NA
14.5	163.114	NA
14.6	163.123	NA
14.7	163.130	NA
14.8	163.140	NA
14.9	163.135	NA
14.10	163.145	NA
14.11	163.153	NA
14.12	163.150	NA
14.13	163.155	NA
14.14	163.117	NA
15.1	137.105	NA
15.10	137.165	NA
15.20	137.155	NA
15.30	137.160	NA
15.40	137.220	NA
15.50	137.180	NA
15.60	137.185	NA
15.70	137.175	NA
15.75	137.170	NA
15.80	137.200	NA
15.90	137.205	NA
15.100	137.225	NA
15.110	137.195	NA
15.120	137.190	NA
15.130	137.300	NA
15.140	137.305	NA
15.150	137.320	NA
15.500	137.250	NA
15.501	137.275	NA
15.502	137.255	NA
15.503	137.260	NA
15.504	137.265	NA
15.505	137.285	NA
15.506	137.270	NA
15.507	137.290	NA
15.508	137.211	NA
15.509	137.215	NA
15.510	137.230	NA
15.511	137.245	NA
15.512	137.240	NA
15.513	137.240	NA
15.514	137.235	NA
15.525	137.250	NA
16.1	139.110	NA
16.2	139.120	NA

Old section	New human section	New animal section[1]
16.3	139.138	NA
16.4	139.140	NA
16.5	139.125	NA
16.6	139.150	NA
16.7	139.180	NA
16.8	139.160	NA
16.9	139.115	NA
16.10	139.155	NA
16.11	139.135	NA
16.12	139.165	NA
16.13	139.121	NA
16.14	139.122	NA
16.15	139.117	NA
17.1	136.3	NA
17.10	136.110	NA
17.20	136.115	NA
17.30	136.130	NA
17.40	136.160	NA
17.50	136.180	NA
17.60	136.165	NA
18.1	131.3	NA
18.2	131.110	NA
18.10	131.135	NA
18.20	131.145	NA
18.30	131.180	NA
18.501	131.155	NA
18.511	131.157	NA
18.515	131.150	NA
18.520	131.130	NA
18.525	131.115	NA
18.530	131.120	NA
18.540	131.125	NA
18.545	131.127	NA
18.550	131.160	NA
18.555	131.162	NA
18.560	131.185	NA
18.565	131.187	NA
18.570	131.164	NA
18.575	131.189	NA
19.499	133.3	NA
19.500	133.113	NA
19.502	133.114	NA
19.503	133.116	NA
19.505	133.136	NA
19.507	133.137	NA
19.510	133.118	NA
19.512	133.119	NA
19.513	133.121	NA
19.515	133.133	NA
19.520	133.162	NA
19.525	133.129	NA
19.530	133.128	NA
19.531	133.131	NA
19.535	133.144	NA
19.537	133.145	NA
19.540	133.195	NA
19.542	133.196	NA
19.543	133.149	NA
19.544	133.185	NA
19.545	133.108	NA
19.547	133.109	NA
19.550	133.160	NA
19.551	133.161	NA
19.555	133.138	NA
19.560	133.142	NA
19.565	133.106	NA
19.567	133.141	NA
19.569	133.164	NA
19.570	133.164	NA
19.575	133.152	NA
19.580	133.153	NA
19.585	133.154	NA
19.590	133.181	NA
19.591	133.111	NA
19.595	133.165	NA
19.600	133.155	NA
19.601	133.157	NA
19.605	133.156	NA
19.606	133.158	NA
19.610	133.183	NA
19.615	133.102	NA
19.620	133.103	NA
19.625	133.104	NA
19.635	133.127	NA
19.637	133.186	NA
19.639	133.140	NA
19.650	133.150	NA
19.655	133.187	NA
19.660	133.188	NA
19.665	133.182	NA
19.670	133.190	NA
19.675	133.191	NA
19.680	133.148	NA
19.685	133.189	NA
19.750	133.169	NA
19.751	133.167	NA
19.755	133.170	NA
19.760	133.171	NA
19.763	133.168	NA
19.765	133.173	NA
19.770	133.174	NA
19.775	133.179	NA
19.776	133.175	NA
19.780	133.180	NA
19.781	133.176	NA
19.782	133.134	NA
19.783	133.178	NA
19.785	133.123	NA
19.787	133.124	NA
19.788	133.135	NA
19.790	133.147	NA
19.791	133.146	NA
19.792	133.193	NA
20.1	135.30	NA
20.2	135.10	NA
20.3	135.40	NA
20.4	135.20	NA
20.5	135.90	NA
20.6	135.65	NA
20.7	135.70	NA
20.8	135.50	NA
22.1	169.3	NA
22.2	169.175	NA
22.3	169.176	NA
22.4	169.177	NA
22.5	169.178	NA
22.6	169.180	NA
22.7	169.181	NA
22.8	169.179	NA
22.9	169.182	NA
25.1	169.140	NA
25.2	169.115	NA
25.3	169.150	NA
26.1	168.111	NA
26.2	168.110	NA
26.3	168.120	NA
26.4	168.121	NA
26.5	168.122	NA
27.1	145.3	NA
27.1 except (g) through (n) and (o) (1) and (4)	146.3	NA

Redesignation Table III

Old section	New human section	New animal section [1]
27.2	145.170(a)	NA
27.3	145.170(b)	NA
27.4	145.170(c)	NA
27.5	145.173	NA
27.6	145.171	NA
27.10	145.115(a)	NA
27.11	145.115(b)	NA
27.12	145.115(c)	NA
27.13	145.118	NA
27.14	145.116	NA
27.15	145.190	NA
27.20	145.175(a)	NA
27.21	145.175(b)	NA
27.22	145.175(c)	NA
27.23	145.178	NA
27.24	145.176	NA
27.25	145.140	NA
27.30	145.125(a)	NA
27.31	145.125(b)	NA
27.32	145.125(c)	NA
27.33	145.128	NA
27.34	145.126	NA
27.35	145.120	NA
27.40	145.135(a)	NA
27.41	145.135(b)	NA
27.42	145.135(c)	NA
27.43	145.138	NA
27.45	145.185(a)	NA
27.46	145.185(b)	NA
27.47	145.185(c)	NA
27.50	145.180(a)	NA
27.51	145.180(b)	NA
27.52	145.180(c)	NA
27.54	146.185(a)	NA
27.55	146.185(b)	NA
27.56	146.185(c)	NA
27.57	145.181	NA
27.60	146.187	NA
27.70	145.130	NA
27.71	145.134	NA
27.73	145.131	NA
27.80	145.110(a)	NA
27.81	145.110(c)	NA
27.90	145.145(a)	NA
27.91	145.145(b)	NA
27.92	145.145(c)	NA
27.99	146.115	NA
27.100	146.125	NA
27.101	146.120	NA
27.102	146.126	NA
27.103	146.121	NA
27.105	146.135	NA
27.106	146.137	NA
27.107	146.140	NA
27.108	146.141	NA
27.109	146.146	NA
27.110	146.150	NA
27.111	146.145	NA
27.112	146.151	NA
27.113	146.152	NA
27.114	146.153	NA
27.115	146.154	NA
27.125	146.133	NA
27.126	146.113	NA
27.127	146.110	NA
27.128	146.111	NA
27.131	146.130	NA
27.150	146.166	NA
27.151	146.169	NA
27.152	146.170	NA
27.153	146.171	NA
27.154	146.172	NA
27.155	146.175	NA
27.156	146.176	NA
27.157	146.177	NA
27.158	146.155	NA
27.159	146.156	NA
27.160	146.158	NA
26.161	146.159	NA
27.162	146.160	NA
27.163	146.161	NA
27.164	146.163	NA
27.165	146.164	NA
27.166	146.165	NA
27.167	146.166	NA
27.168	146.167	NA
28.1	152.126(a)	NA
28.2	152.126(b)	NA
29.1	150.110	NA
29.2	150.140	NA
29.3	150.160	NA
29.4	150.141	NA
29.5	150.161	NA
30.1	168.180	NA
30.2	168.140	NA
30.3	168.130	NA
30.4	168.160	NA
31.1	165.175	NA
36.3	161.173(c)	NA
36.5	161.145(a)	NA
36.6	161.145(c)	NA
36.10	161.130	NA
36.11	161.131	NA
36.12	161.132	NA
36.13	161.133	NA
36.14	161.134	NA
36.15	161.135	NA
36.16	161.136	NA
36.17	161.137	NA
36.18	161.138	NA
36.19	161.139	NA
36.20	161.140	NA
36.30	161.175	NA
36.31	161.176	NA
37.1	161.190(a)	NA
37.3	161.190(c)	NA
37.10	161.170(a)	NA
37.12	161.170(c)	NA
42.1	160.100	NA
42.10	160.115	NA
42.20	160.110	NA
42.30	160.105	NA
42.40	160.180	NA
42.50	160.190	NA
42.60	160.185	NA
42.70	160.140	NA
42.71	160.150	NA
42.72	160.145	NA
45.1	166.110	NA
46.1	164.150	NA
46.51	164.110	NA
46.52	164.120(c)	NA
50.1	158.3	NA
50.2	158.170(a)	NA
50.3	158.170(b)	NA
51.1	155.170(a)	NA
51.2	155.170(b)	NA
51.3	155.170(c)	NA
51.4	155.172(a)	NA
51.5	155.172(b)	NA
51.6	155.172(c)	NA
51.10	155.120(a)	NA

Old section	New human section	New animal section [1]
51.11	155.120(b)	NA
51.20	155.130(a)	NA
51.21	155.130(b)	NA
51.22	155.130(c)	NA
51.30	155.131(a)	NA
51.32	155.131(c)	NA
51.503	155.201(c)	NA
51.990	155.200	NA
53.1	156.145	NA
53.5	156.147	NA
53.10	155.194	NA
53.20	155.192	NA
53.30	155.191	NA
53.40	155.190(a)	NA
53.41	155.190(b)	NA
53.42	155.190(c)	NA
80.1	105.85	NA
85.1	197.810	NA
85.2	197.812	NA
85.3	197.820	NA
85.4	197.825	NA
85.5	197.829	NA
85.6	197.830	NA
85.7	197.840	NA
85.8	197.850	NA
85.9	197.855	NA
85.10	197.860	NA
85.11	197.870	NA
85.12	197.880	NA
85.13	197.885	NA
85.14	197.815	NA
85.16	197.310	NA
85.17	197.312	NA
85.18	197.320	NA
85.19	197.325	NA
85.20	197.329	NA
85.21	197.330	NA
85.22	197.340	NA
85.23	197.350	NA
85.24	197.355	NA
85.25	197.360	NA
85.26	197.370	NA
85.27	197.380	NA
85.28	197.385	NA
85.29	197.315	NA
90.1	108.3	508.3
90.2	108.19	508.19
90.3	108.5	508.5
90.4	108.7	508.7
90.5	108.10	508.10
90.6	108.6	508.6
90.7	108.12	508.12
90.20	108.35	508.35

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[1] The text of the animal food regulations listed in this column are set forth in the fourteenth recodification document published in the FEDERAL REGISTER of Sept. 10, 1976 (41 FR 38618).

Redesignation Table IV

At 42 FR 15553, March 22, 1977, a document was published which reorganized and republished all of Subchapter A of the general regulations.

The following table shows the relationship of the Code of Federal Regulations under former section numbers under Subchapter A and the newly assigned numbers under the subchapter:

Old section	New section	Old section	New section
1.1	1.1	2.117	12.32
1.1a	1.23	2.118	12.35
1.1b	1.20	2.119	12.37
1.1c	1.24	2.120	12.38
1.1d	1.35	2.130	12.40
1.1e	1.31	2.131	12.45
1.2	1.3	2.135	12.50
1.3	1.21	2.140	12.60
1.4	7.12	2.141	12.62
1.5	7.13	2.142	12.70
1.315	1.83	2.143	12.75
1.316	1.90	2.144	12.78
1.317	1.91	2.150	12.80
1.318	1.94	2.151	12.82
1.319	1.95	2.152	12.83
1.320	1.96	2.153	12.85
1.321	1.97	2.154	12.87
1.322	1.99	2.155	12.89
1.700	2.10	2.156	12.90
2.1	10.1	2.157	12.91
2.3	10.3	2.158	12.92
2.4	10.10	2.159	12.93
2.5	10.20	2.160	12.94
2.6	10.25	2.161	12.95
2.7	10.30	2.162	12.96
2.8	10.33	2.163	12.97
2.9	10.35	2.164	12.98
2.10	10.40	2.165	12.99
2.11	10.45	2.170	12.100
2.12	10.50	2.171	12.105
2.13	10.55	2.172	12.110
2.14	10.60	2.173	12.115
2.15	10.65	2.180	12.120
2.16	10.70	2.181	12.125
2.17	10.75	2.182	12.130
2.18	10.80	2.183	12.139
2.19	10.85	2.190	12.140
2.20	10.90	2.191	12.159
2.21	10.95	2.200	13.1
2.22	10.100	2.201	13.5
2.23	10.105	2.202	13.10
2.24	10.110	2.203	13.15
2.25	10.19	2.204	13.20
2.100	12.1	2.205	13.25
2.110	12.20	2.206	13.30
2.111	12.21	2.207	13.40
2.112	12.22	2.208	13.45
2.113	12.24	2.209	13.50
2.114	12.26	2.300	14.1
2.115	12.28	2.301	14.40
2.116	12.30	2.302	14.55

Old section	New section
2.303	14.5
2.304	14.25
2.305	14.20
2.306	14.30
2.307	14.22
2.308	14.31
2.309	14.39
2.310	14.33
2.311	14.35
2.312	14.29
2.313	14.60
2.314	14.61
2.315	14.70
2.316	14.75
2.317	14.65
2.318	14.27
2.319	14.7
2.320	14.10
2.321	14.15
2.322	14.19
2.330	14.80
2.331	14.82
2.332	14.84
2.333	14.86
2.334	14.90
2.335	14.95
2.340	14.100
2.350	14.120
2.351	14.122
2.352	14.125
2.353	14.127
2.354	14.130
2.360	14.140
2.361	14.142
2.362	14.145
2.363	14.147
2.364	14.155
2.370	14.160
2.371	14.171
2.372	14.174
2.373	14.172
2.400	15.1
2.401	15.20
2.402	15.21
2.403	15.30
2.404	15.25
2.405	15.40
2.406	15.45
2.500	16.1
2.501	16.5
2.502	16.42
2.505	16.40
2.506	16.42
2.510	16.22
2.511	16.24
2.512	16.60
2.513	16.80
2.514	16.85
2.515	16.95
2.516	16.119
2.520	16.120
2.600	19.1
2.610	19.5
2.611	19.6
2.612	19.10
2.613	19.21
2.620	19.55
2.621	19.45
2.700	7.1
2.703	7.3
2.705	7.84
2.706	7.85
2.707	7.87
3.13	2.25
3.73	2.5
3.89	2.19
3.700	2.110
4.1	20.1
4.2	20.2
4.3	20.3
4.20	20.20
4.21	20.21
4.22	20.22
4.23	20.23
4.24	20.24
4.25	20.25
4.26	20.26
4.27	20.27
4.28	20.28
4.29	20.29
4.30	20.30
4.31	20.31
4.32	20.32
4.40	20.40
4.41	20.41
4.42	20.42
4.43	20.43
4.44	20.44
4.45	20.45
4.46	20.46
4.47	20.47
4.48	20.48
4.49	20.49
4.50	20.50
4.51	20.51
4.52	20.52
4.53	20.53
4.60	20.60
4.61	20.61
4.62	20.62
4.63	20.63
4.64	20.64
4.80	20.80
4.81	20.81
4.82	20.82
4.83	20.83
4.84	20.84
4.85	20.85
4.86	20.86
4.87	20.87
4.88	20.88
4.89	20.89
4.90	20.90
4.91	20.91
4.100	20.100
4.101	20.101
4.102	20.102
4.103	20.103
4.104	20.104
4.105	20.105
4.106	20.106
4.107	20.107
4.108	20.108
4.109	20.109
4.110	20.110
4.111	20.111
4.112	20.112
4.113	20.113
4.114	20.114
4.115	20.115
4.116	20.116
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